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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2023-2189; Airspace Docket No. 22-AAL-43]

RIN 2120-AA66

Revocation of Colored Federal Airways Amber 3 (A-3), Amber 17 (A-17), and Green 16 (G-16) in Alaska

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airways A-3, A-17, and G-16 in Alaska due to the pending decommissioning of the Put River, Evansville, Chandalar Lake, Nuiqsut Village, Browerville, and Wainwright Village Nondirectional Radio Beacons (NDB).

DATES: Effective date 0901 UTC, December 26, 2024. 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: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267-8783.

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; 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 (ATS) route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

History

The FAA published a NPRM for Docket No. FAA 2022-2189 in the **Federal Register** (88 FR 82283; November 24, 2023), proposing to revoke A-3, A-17, and G-16 in Alaska. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Differences From the NPRM

The NPRM published for Docket No. FAA-2023-2189 in the **Federal Register** (88 FR 82283; November 24, 2023) contained a typographical error in the regulatory text of the document. The regulatory text of the NPRM listed A-2 as one of the airways proposed to be revoked. This was an error and the correct airway proposed to be revoked is A-3. Additionally, the NPRM title contained an error by referring to Gold 16 (G-16) instead of Green 16 (G-16). This rule corrects these errors.

Incorporation by Reference

Colored Federal airways are published in paragraph 6009 of FAA Order JO 7400.11, Airspace Designations and Reporting Points,

which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is finalizing an amendment to 14 CFR part 71 to revoke Colored Federal airways A-3, A-17, and G-16 in Alaska due to the pending decommissioning of their supporting Navigational Aids (NAVAID).

A-3: This action revokes A-3 in its entirety.

A-17: This action revokes A-17 in its entirety.

G-16: This action revokes G-16 in its entirety.

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 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 airspace action of revoking A-3, A-17, and G-16 in Alaska 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 5–6.5k, which categorically excludes from further environmental review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. 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. Accordingly, 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 7400.11], Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6009(a) Green Federal Airways.

G–16 [Removed]

Paragraph 6009(c) Amber Federal Airways.

A–3 [Removed]

* * * * *

A–17 [Removed]

* * * * *

Issued in Washington, DC, on October 3, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–23201 Filed 10–9–24; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9994]

RIN 1545–BP55

Section 367(d) Rules for Certain Repatriations of Intangible Property

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule.

SUMMARY: This document contains final regulations that terminate the continued application of certain tax provisions arising from a previous transfer of intangible property to a foreign corporation when the intangible property is repatriated to certain United States persons. The final regulations affect certain United States persons that previously transferred intangible property to a foreign corporation.

DATES:

Effective date: These regulations are effective on October 10, 2024.

Applicability date: For dates of applicability, see §§ 1.367(d)–1(j)(2), 1.904–(q)(3), 1.951A–7(e), and 1.6038B–1(g)(8).

FOR FURTHER INFORMATION CONTACT:

Concerning the final regulations other than § 1.904–4, Brittany N. Dobi (202) 317–6937; concerning § 1.904–4, Jeffrey L. Parry, (202) 317–6936 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Authority

This document contains final additions and amendments to 26 CFR part 1 (final regulations) under section 367(d) of the Internal Revenue Code (Code) regarding the termination of the continued application of certain tax provisions arising from a previous transfer of intangible property to a foreign corporation when the intangible property is repatriated to certain United States persons. The primary provisions of the final regulations are issued

pursuant to the express delegations of authority to the Secretary of the Treasury (or her delegate) provided under sections 367(d) and 6038B. The provisions of the final regulations related to foreign branch income are issued pursuant to the express delegations of authority provided under sections 904(d)(2)(J) and (d)(7). The final regulations are also issued under the express delegation of authority under section 7805(a).

Background

On May 3, 2023, the Department of the Treasury (Treasury Department) and the IRS published a notice of proposed rulemaking (REG–124064–19) in the Federal Register (88 FR 27819) under section 367 (the proposed regulations). The proposed regulations were intended to address simple, common fact patterns involving repatriations of intangible property by terminating the continued application of section 367(d) when a transferee foreign corporation repatriates intangible property subject to section 367(d) to a qualified domestic person when certain reporting requirements are satisfied. The proposed regulations also included a rule coordinating the application of section 367(d) and the provisions in § 1.904–4(f)(2)(vi)(D) that apply the principles of section 367(d) to determine the appropriate amount of gross income attributable to a foreign branch. A “repatriation” denotes a subsequent transfer of intangible property to the U.S. transferor or a United States person (U.S. person) related to the U.S. transferor.

Summary of Comments and Explanation of Revisions

I. In General

Five comments were submitted on the proposed regulations, which are available at <https://www.regulations.gov> or upon request. No public hearing on the proposed regulations was requested or held.

This Summary of Comments and Explanation of Revisions describes those comments and the revisions made in response to those comments. The comments also made various requests for future guidance, which the Treasury Department and the IRS will consider as part of a potential future rulemaking addressing, among other things, general issues under section 367(d).

II. Definition of Qualified Domestic Person

A. In General

To terminate the continued application of section 367(d) upon a

repatriation of intangible property, the proposed regulations required the recipient of the intangible property to be a qualified domestic person. The proposed regulations defined a qualified domestic person by reference to an “initial U.S. transferor,” a “qualified successor,” or a U.S. person that is either an individual or “qualified corporation” related to either the initial U.S. transferor or qualified successor. *See* proposed § 1.367(d)–1(f)(4)(iii).

As the preamble to the proposed regulations explained in part I.C of the Explanation of Provisions, the definition of qualified domestic person was based on the principle that it is generally appropriate to terminate the continued application of section 367(d) only when all the income produced by the intangible property during its useful life, and all gain recognized on a disposition of the intangible property, will be subject to current tax in the United States as to the qualified domestic person while that person holds the property. *See* 88 FR 27819, 27824. The proposed regulations further described how, in the case of a repatriation to an initial U.S. transferor, the repatriation restored the circumstances that existed at the time of the original section 367(d) transfer. *See Id.*

B. Partnerships

The proposed regulations neither treated a domestic partnership as a qualified domestic person, nor adopted an approach that would treat a partnership as an aggregate of its partners (aggregate approach) for purposes of determining qualified domestic person status. One comment suggested that the Treasury Department and the IRS modify the definition of qualified domestic person to include partnerships in which all of the partners in the partnership would themselves be qualified domestic persons, or partnerships that made the original outbound transfer of the intangible property subject to section 367(d) when there is substantial continuity of ownership of that partnership during the period beginning on the date of the initial section 367(d) transfer and ending on the date of the repatriation of the intangible property. As part of the modification, the comment also described various approaches for addressing the concerns identified in the proposed regulations regarding, for example, the potential for post-repatriation changes to partnership allocations or liquidation rights to frustrate the purposes of the proposed regulations if a partnership, or a partner in the partnership, were permitted as a

qualified domestic person in certain cases. *See* 88 FR 27819, 27824 for a discussion of those concerns. Specifically, the comment suggested that the final regulations, in adopting the modification, could limit its application by requiring a specific period after the repatriation during which the ownership or interests in the partnership could not change. Additionally, the comment suggested that, to provide flexibility while protecting against the concerns outlined in the proposed regulations, the final regulations could allow the Commissioner to exercise discretion at a taxpayer’s request to determine that a post-distribution change in the ownership of the partnership, or in the economic rights of the partners with respect to the intangible property, would not taint the partnership’s status as a qualified domestic person. Finally, the comment also described more general, long-standing issues under section 367(d) related to the treatment of partnerships within the section 367(d) regime, and ultimately suggested that resolution of those issues should not impede finalizing the proposed regulations.

The final regulations do not adopt this comment and therefore adopt the definition of qualified domestic person from the proposed regulations without change. The issues identified by the comment, along with potential solutions to those issues, were acknowledged in the preamble to the proposed regulations, and the Treasury Department and the IRS have determined that the approach outlined in the proposed regulations continues to strike the appropriate balance between implementing the general purpose and scope of the proposed regulations (ensuring that only appropriate repatriations terminate the continued application of section 367(d)) and concerns regarding administrability and compliance. The solutions described in the comment, like the alternatives described in the proposed regulations, would not achieve this balance because the solutions would either expand the scope of the proposed regulations in an inappropriate manner (that is, by expanding the basic principle upon which the proposed regulations rests), or the solutions would, given the relatively narrow scope of the proposed regulations, impose an undue burden on taxpayers and the IRS. *See* 88 FR 27819, 27824 (describing, with respect to the latter, an approach modeled off of the rules in §§ 1.367(a)–3 and 1.367(a)–8 regarding gain recognition agreements and noting that approach would be

“unworkable due to the compliance and administrative burden.”).

Another comment described general, long-standing issues under section 367(d) related to the treatment of partnerships. These issues were generally identified in the proposed regulations. *See id.* For example, the comment pointed to §§ 1.367(a)–1T(c)(3)(i) and 1.367(d)–1T(a), which apply an aggregate approach upon an initial outbound transfer. The comment did not include any explicit suggestion for change regarding the proposed regulations, but the Treasury Department and the IRS may consider these issues as part of future rulemaking.

C. S Corporations

As described in part I.A of this Summary of Comments and Explanation of Revisions, the proposed regulations limited qualified domestic person status to “qualified corporations” in the case of a qualified successor or in the case of a U.S. person related to either the initial U.S. transferor or qualified successor. *See* proposed § 1.367(d)–1(f)(4)(iii). A qualified corporation, in relevant part, did not include an S corporation (as defined in section 1361(a)). *See Id.*

One comment suggested that the final regulations allow S corporations as qualified corporations. The comment noted that the shareholders of an S corporation must generally be U.S. individuals subject to U.S. taxation, which ensures that income attributable to intangible property held by an S corporation would be subject to U.S. taxation (though the comment noted that the limitation is not absolute, as certain plans described in section 401(a) may be shareholders of an S corporation).

Section 512(e)(3) excludes a non-individual shareholder that is an employee stock ownership plan (ESOP) (as defined in section 4975(e)(7) from the scope of section 512(e)(1), which provides that, in the case of certain non-individual shareholders of the S corporation, any item of income, gain, loss, or deduction, and any gain or loss on the disposition of stock in the S corporation, is taken into account by such non-individual shareholders as unrelated business taxable income (UBTI). As a result, the pro rata share of an S corporation’s items of income taken into account by an ESOP shareholder is not subject to current taxation as UBTI. As noted in part I.A of this Summary of Comments and Explanation of Revisions, a principle for the definition of qualified domestic person is that termination of the continued application of section 367(d)

should occur only when all the income produced by the intangible property, as well as gain recognized on a disposition of the intangible property, is subject to current tax in the United States. In the case of an S corporation, that result is not guaranteed.

The final regulations, therefore, do not adopt this comment and retain the definition of qualified domestic person from the proposed regulations without change. The Treasury Department and the IRS considered alternative approaches to address this comment—such as an aggregate approach, with prohibitions applicable to S corporation shareholders that are ESOPs—but determined that such approaches were effectively unworkable due to the compliance and administrative burden discussed in part II.B of this Summary of Comment and Explanation of Revisions in connection with the comment on partnerships.

III. Qualified Domestic Person's Adjusted Basis in Repatriated Intangible Property

Proposed § 1.367(d)–1(f)(4)(iv) provided rules regarding a qualified domestic person's adjusted basis in the intangible property it receives in a repatriation. The proposed regulations described how these rules were intended to achieve an appropriate result regarding a qualified domestic person's adjusted basis in intangible property upon a repatriation, but that general rules regarding adjusted basis under section 367(d) (and not in the context of a repatriation of intangible property to a qualified domestic person) would be addressed in future rulemaking. See 88 FR 27819, 27824, and 27825.

One comment described how existing uncertainty regarding the treatment of adjusted basis of intangible property subject to section 367(d) may be implicated when that intangible property is repatriated. The comment noted that any solution would necessarily represent a broad solution to existing section 367(d) issues, instead of one limited to the proposed regulations, so the comment recommended the Treasury Department and the IRS address this issue in future rulemaking. Another comment suggested that, when a transferee foreign corporation incurs expenditures with respect to repatriated intangible property after the initial outbound transfer, proposed § 1.367(d)–1(f)(4)(iv) should be modified to allow a qualified domestic person's adjusted basis in repatriated intangible property to reflect those expenditures, reduced by any attributable amortization allowed

or allowable to the transferee foreign corporation.

As noted in the proposed regulations, proposed § 1.367(d)–1(f)(4)(iv) operated “in a manner intended to reach an appropriate result regarding a qualified domestic person's basis in repatriated intangible property” until future rulemaking is issued that can address general basis rules under section 367(d). See *id.* The Treasury Department and the IRS, in agreement with the first comment, continue to believe that any resolution of these issues necessarily implicates broader issues under section 367(d) and, as such, is beyond the scope of this rulemaking. Proposed § 1.367(d)–1(f)(4)(iv) is therefore finalized without change, though the Treasury Department and the IRS may revisit these issues as part of future rulemaking.

IV. Required Adjustments Related to an Annual Section 367(d) Inclusion

The proposed regulations provided that the deemed annual payment under section 367(d) by the transferee foreign corporation is treated as an allowable deduction that must be allocated and apportioned to the transferee foreign corporation's classes of gross income in accordance with §§ 1.882–4(b)(1), 1.954–1(c), and 1.960–1(c) and (d) (as applicable). See proposed § 1.367(d)–1(c)(2)(ii) and (e)(2)(ii). These provisions, described as “minor clarifications” in the preamble to the proposed regulations, clarified “that the allowable deduction is allocated and apportioned under the provisions cited in the previous sentence potentially to any class (or classes) of gross income (as appropriate) rather than solely to gross income subject to subpart F in all circumstances.” See 88 FR 27819, 27822, and 27825.

One comment suggested that the proposed regulations were unclear as to whether the allowable deduction described in proposed § 1.367(d)–1(c)(2)(ii) and (e)(2)(ii) was limited to the listed provisions (§§ 1.882–4(b)(1), 1.954–1(c), and 1.960–1(c) and (d)) or whether such deduction was more generally available (for example, as a deduction under section 162). The comment posited that the latter approach was more appropriate and requested that the final regulations clarify that the allowable deduction may be allowed as a deduction under section 162. In support, the comment described how, in the case of certain transfers of intangible property to a U.S. person that is not a qualified domestic person, “excessive U.S. taxation” could result if the allowable deduction were limited to the listed provisions, which are

provisions relevant to determinations with respect to foreign corporations.

The final regulations do not adopt this comment. The proposed regulations terminated the continued application of section 367(d) upon certain, rather than all, subsequent transfers of intangible property to a U.S. person (that is, upon a repatriation to a qualified domestic person if certain reporting requirements are met). See 88 FR 27819, 27821, and 27822. The comment, if adopted, would effectively terminate the continued application of section 367(d) by, for example, providing a deduction under section 162 corresponding to each annual inclusion under section 367(d). Indeed, as the proposed regulations explained, the solution contained in the proposed regulations was premised, in relevant part, on the fact that “the deemed (substituted) transferee foreign corporation is not allowed a deduction that could reduce taxable income, even though that deemed transferee foreign corporation is the U.S. transferor or a related U.S. person.” See *id.* Thus, a fundamental premise underlying the proposed regulations, and the existing section 367(d) regulations, is that an allowable deduction, instead of being generally available, is limited to the provisions listed in the proposed regulations (§§ 1.882–4(b)(1), 1.954–1(c), and 1.960–1(c) and (d)). To adopt the comment's suggestion would therefore be inconsistent with the proposed regulations and section 367(d) generally.

The comment also suggested that, when a subsequent transfer of intangible property results in treating the same entity as U.S. transferor and transferee foreign corporation under the section 367(d) regulations, the continued application of section 367(d) should terminate by reason of that convergence. As support, the comment cited to a case and guidance involving circumstances in which a taxpayer acquired its own debt. The Treasury Department and the IRS do not agree with this suggestion for the reasons described in the preceding paragraph, and references to cases or guidance involving a taxpayer acquiring its own debt are not instructive for, nor consistent with, the statutory and regulatory framework of section 367(d). Section 367(d) relies upon a statutory fiction that imposes a notional regime with a prescribed payor and payee, and the regulations describe cases in which a successor succeeds to the notional payment on both sides of the construct. For example, § 1.367(d)–1T(e)(1) provides that a related person can succeed an initial U.S. transferor for purposes of including income under section 367(d), and § 1.367(d)–1T(f)(3) provides that a related person can

succeed to the payor side of the deemed payment fiction. Where intangible property is returned to the original U.S. transferor, that U.S. transferor is also the successor transferee under the statutory and regulatory framework of section 367(d), and, under the express language of § 1.367(d)–1T(f)(3), the annual inclusion under section 367(d) continues. This is precisely the issue the proposed regulations were intended to address, and new regulations providing a rule for terminating an annual inclusion stream would have been largely unnecessary if the deemed payment construct collapsed automatically in such cases. Instead, this Treasury Decision provides the exclusive means by which the continued application of section 367(d) may be terminated by reason of a subsequent transfer of intangible property to a U.S. person.

V. Multiple Transfers Before Repatriation

One comment suggested changes to the proposed regulations to accommodate repatriations preceded by certain transfers of intangible property subject to section 367(d) between related foreign corporations. To illustrate this suggestion, the comment posited an example pursuant to which a repatriation was first preceded by a distribution under section 311 of the intangible property (first section 311 distribution) from one CFC (original transferee foreign corporation, or TFC) to another CFC (successor TFC). The successor TFC then distributes the intangible property under section 311 to a qualified domestic person (second 311 distribution) in a transaction with respect to which the successor TFC did not recognize gain or loss (under the theory that successor TFC's adjusted basis in the intangible property equaled the intangible property's fair market value).

On those modified facts, the comment described how the original TFC could recognize gain subject to U.S. taxation by reason of the first section 311 distribution (not under section 367(d), but rather under, for example, section 951A(a) as to a United States shareholder), and the qualified domestic person could recognize that same amount of gain upon the repatriation after the second 311 distribution under the proposed regulations (by reason of the application of the gain recognition rule in proposed § 1.367(d)–1(f)(4)(ii)(B), under which gain is determined by reference to the U.S. transferor's former adjusted basis in the property). And, because the successor TFC is the TFC at the time of the repatriation (that is, at

the time of the second section 311 distribution), the required adjustments described in proposed § 1.367(d)–1(f)(2) would apply by reference to the successor TFC, which did not recognize gain or loss on the repatriation under the theory described above, rather than to the original TFC, which recognized gain on the first section 311 distribution. To address this concern, the comment suggested modifying the proposed regulations in a manner that would effectively negate a prior transfer that was subject to tax under a separate regime (for example, section 951A).

The example provided in the comment highlights significant potential interactions between the operation of section 367(d) and other generally operative provisions in the Code and regulations. For example, § 1.367(d)–1T(f)(3) explicitly provides that the ongoing annual royalty construct is unaffected by the taxable distribution of intangible property from the original TFC to the successor TFC in the first section 311 distribution, and § 1.367(d)–1T(d)(1) and (f)(1) are clear that the amount of income recognized by the U.S. transferor upon a later indirect or direct disposition of intangible property to an unrelated person is determined using the transferor's original basis in the property. However, the distribution of the intangible property from the original TFC to the successor TFC described in the comment's example might result in taxable gain to the original TFC that would be treated as tested income under section 951A, notwithstanding the lack of an acceleration of income under section 367(d). Similarly, the successor TFC might take the intangible property with a fair market value basis under section 301(d), even though that increased basis would not be available to reduce gain under section 367(d). Essentially, the example posited in the comment highlights that it may be possible to recognize income under both sections 951A and 367(d) with respect to the same property in some fact patterns where separate transactions occur in separate foreign corporations, notwithstanding that that result would not occur in cases where the property is not transferred among multiple foreign corporations. Coordinating potential disparities between income recognition under section 367(d) as compared to other generally applicable provisions of the Code, and potential disparities in tax basis for purposes of section 367(d) as compared to adjusted basis for other purposes, is beyond the scope of this rulemaking. The request for additional

guidance addressing multiple related transfers, therefore, is not adopted.

VI. Reporting

As a condition for terminating the application of section 367(d) with respect to repatriated intangible property, proposed § 1.367(d)–1(f)(4)(i)(B) would have required a U.S. transferor to provide the information described in proposed § 1.6038B–1(d)(2)(iv). If a U.S. transferor failed to provide that information, the repatriation was subject to proposed § 1.367(d)–1(f)(3) such that the section 367(d) regulations, including the requirement to take an annual inclusion into account over the useful life of the intangible property, continued to apply. However, a U.S. transferor was eligible for relief under the proposed regulations if proposed § 1.367(d)–1(f)(4)(i)(B)(2) would have applied to the subsequent transfer of intangible property but for the fact that the required information was not provided and the U.S. transferor, upon becoming aware of the failure, promptly provided the required information, explained its failure to comply, and met certain other requirements (if applicable).

One comment requested clarifications of the reporting and relief provisions. First, the comment requested that the final regulations clarify whether relief for a failure to comply is, in relevant part, also conditioned on the U.S. transferor timely filing one or more amended returns for the taxable year in which the subsequent transfer occurred and succeeding years, and, if the U.S. transferor is under examination when an amended return is filed, providing a copy of the amended return(s) to the IRS personnel conducting the examination. The Treasury Department and the IRS adopt this comment by revising of § 1.367(d)–1(f)(5) to clarify that the relief for a failure to comply is conditioned upon the requirements listed in the previous sentence (if applicable).

The comment also requested that the Treasury Department and the IRS consider prescribing in the future a particular form for filing the required information under proposed § 1.367(d)–1(f)(5). The Treasury Department and the IRS will consider prescribing a particular form as part of future improvements to reporting with respect to section 367(d) generally. However, to provide taxpayers with additional guidance on the manner for providing a U.S. transferor's explanation for its failure to comply to the IRS, the final regulations provide an eFax number for such purpose (and, if a taxable year of the U.S. transferor is under examination, that information should

instead be provided to the IRS personnel conducting the examination).

Finally, the comment suggested clarifications or modifications to the requirements in proposed § 1.367(d)–1(f)(5) that a U.S. transferor “promptly” address its failure to file and to the way the U.S. transferor provides the remedial information (that is, to the Director of Field Operations, Cross Border Activities Practice Area of Large Business & International, or any successor to that role). The comment suggested that “promptly” does not provide sufficient guidance to taxpayers (the comment requested a prescribed period) and the comment asserted that it is unusual for regulations to require a taxpayer to provide information directly to a specified official within the IRS. The final regulations do not adopt these suggestions. The Treasury Department and the IRS believe that “promptly” requiring the U.S. transferor to address its failure to comply, rather than providing a specific period, allows flexibility so that the relief may apply as appropriate to a taxpayer’s particular facts and circumstances. Additionally, proposed § 1.367(d)–1(f)(5) is modeled on similar relief provisions in other contexts (for example, §§ 1.367(a)–8(p) and 1.721(c)–6(f)).

The Treasury Department and the IRS clarify proposed § 1.367(d)–1(f)(5) by striking the last clause that appeared in the second sentence. That sentence described the consequences of a failure to comply, namely the continued application of the annual inclusion stream pursuant to proposed § 1.367(d)–1(f)(3) and application of the gain recognition rule of proposed § 1.367(d)–1(f)(4)(i)(A). If the failure to comply is remedied, the rules of the proposed regulations are treated as satisfied as of the date of the repatriation (so, the repatriation terminates the continued application of section 367(d) and the U.S. transferor, if applicable, would take a partial annual inclusion into account pursuant to proposed § 1.367(d)–1(f)(4)(i)(B)(1)).

VII. Clarification to Example 3

Proposed § 1.367(d)–1(f)(6)(ii)(C) (Example 3) illustrated the determination of a qualified domestic person’s adjusted basis in intangible property under the proposed regulations. In that example, TFC transferred the intangible property to USS (a qualified domestic person as defined in proposed § 1.367(d)–1(f)(4)(iii)) in an exchange described in section 351(b) pursuant to which TFC recognized \$50x of gain and USP recognized \$50x of gain under proposed § 1.367(d)–1(f)(4)(i)(A). The analysis

under proposed § 1.367(d)–1(f)(6)(ii)(C)(2) was, and remains in this Treasury decision, limited to the determination of USS’s adjusted basis in the intangible property.

One comment requested, in relevant part, that the final regulations clarify that TFC’s earnings and profits and gross income arising by reason of the repatriation are reduced by the amount of gain recognized by USP under proposed § 1.367(d)–1(f)(4)(i)(A) (\$50x). The Treasury and the IRS adopt the comment by clarifying in the facts of the example that, under § 1.367(d)–1(f)(2)(i), TFC will reduce its earnings and profits and gross income by \$50x, the amount arising by reason of the repatriation and the amount of gain recognized by USP under § 1.367(d)–1(f)(4)(i)(A).

VIII. Section 904(d) Foreign Branch Income Rules

Proposed § 1.904–4(f)(2)(vi)(D)(4) described the application of the principles of section 367(d) to subsequent transfers of intangible property in determining adjustments to the amount of gross income attributable to a foreign branch under § 1.904–4(f)(2)(vi)(D). Specifically, the proposed regulations would have provided that each transfer to which § 1.904–4(f)(2)(vi)(D) applies is considered independently from any other preceding or subsequent transfer of the intangible property, with the result that the subsequent transfer rules in the regulations under section 367(d), including the rules for repatriations provided in the proposed regulations, do not apply in determining gross income attributable to a foreign branch under § 1.904–4(f)(2)(vi)(D). See 88 FR 27819, 27825, and 27826.

One comment requested that the Treasury Department and the IRS finalize the provisions of the proposed regulations without finalizing proposed § 1.904–4(f)(2)(vi)(D)(4). The comment suggested that such an approach could allow for further consideration of ways to simplify the application of section 367(d) principles in § 1.904–4(f)(2)(vi)(D). The comment suggested that instead of finalizing proposed § 1.904–4(f)(2)(vi)(D)(4), that provision could be adopted as a temporary regulation, or alternatively, this preamble could state that, until the implementation of final regulations addressing this issue, the Treasury Department and the IRS intend that rules related to section 367(d) and subsequent transfer will not apply for purposes of section 904(d).

A broader reconsideration of the application of section 367(d) principles in § 1.904–4(f)(2)(vi)(D) is beyond the

scope of these final regulations. The Treasury Department and the IRS believe it is necessary to finalize proposed § 1.904–4(f)(2)(vi)(D)(4) to ensure the proper application of the foreign branch income rules under § 1.904–4(f)(2)(vi)(D) as those rules currently stand. This is because, as explained in the preamble to the proposed regulations, while § 1.904–4(f)(2)(vi)(D) relies on the principles of section 367(d) to determine the appropriate amount of gross income that is attributable to a foreign branch, the purposes of section 367(d) and § 1.904–4(f)(2)(vi)(D) are different. See 88 FR 27819, 27825 (providing that, with respect to § 1.904–4(f)(2)(vi)(D), “[i]f there are multiple transfers of an item of intangible property over time, each transfer must be separately evaluated and could result in differing amounts of deemed annual payments depending on any interim changes in the value of the intangible property between successive transfers . . . these proposed regulations provide that each successive transfer to which § 1.904–4(f)(2)(vi)(D) applies is considered independently from any other preceding or subsequent transfers.”). Accordingly, the final regulations do not adopt this comment and proposed § 1.904–4(f)(2)(vi)(D) is finalized without change.

IX. Applicability Dates

The proposed regulations were generally proposed to apply to subsequent dispositions of intangible property occurring on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. See proposed §§ 1.367(d)–1(j)(2), 1.904–4(q)(3), and 1.6038B–1(g). Comments recommended that the proposed regulations apply retroactively.

The Treasury Department and the IRS generally consider several factors when evaluating whether a rule should apply retroactively on an elective basis. For example, and as relevant to the proposed regulations, retroactive application may be more compelling where the regulations are issued with respect to new legislation, or where retroactive application is necessary to achieve certain policy objectives. The Treasury Department and the IRS also evaluate the additional administrative burden likely to result from retroactive application. Finally, where the regulations represent a change in existing regulations, consideration is given to whether retroactive application could advantage certain taxpayers over similarly situated taxpayers, based on whether the relevant taxable year remains open for the taxpayer to amend

their return to take advantage of the change. The Treasury Department and the IRS have determined that, on balance, these factors, though not representing an exhaustive list of factors, weigh against permitting the retroactive application of the final regulations and therefore do not adopt these comments.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

The collection of information contained in these regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–0026. The collection of information in these final regulations is in § 1.6038B–1(d)(2)(iv). This information is necessary to ensure that proposed § 1.367(d)–1(f)(4) is appropriately applied to the subsequent transfer. The collection of information is required to comply with section 367(d). The likely respondents are domestic corporations. Burdens associated with these requirements will be reflected in the burden for Form 926, *Return by a U.S. Transferor of Property to a Foreign Corporation*.

Estimated total annual reporting burden is 1,601 hours.

Estimated average annual burden per respondent is 2.4 hours.

Estimated number of respondents is 667.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any Internal Revenue law. Generally, tax returns and tax return information are confidential, as required by section 6103.

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these final regulations will

not have a significant economic impact on a substantial number of small entities.

The Treasury Department and the IRS do not have data readily available to assess the number of small entities potentially affected by the final regulations. However, entities potentially affected by these proposed regulations are generally not small entities, because of the resources and investment necessary to develop intangible property and, once so developed, transfer the intangible property to a foreign corporation. Therefore, the Treasury Department and the IRS have determined that there will not be a substantial number of domestic small entities affected by the final regulations. Consequently, the Treasury Department and the IRS certify that the final regulations will not have a significant economic impact on a substantial number of small entities.

IV. Section 7805(f)

Pursuant to section 7805(f) of the Code, the proposed regulations (REG–113839–22) preceding these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business, and no comments were received.

V. Unfunded Mandates Reform Act

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

VI. Executive Order 13132: Federalism

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

preempt State law within the meaning of the Executive order.

Drafting Information

The principal author of these regulations is Brittany N. Dobi, of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, the Treasury Department and the IRS amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

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

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

Section 1.367(d)–1 also issued under 26 U.S.C. 367(d).

* * * * *

§ 1.367(a)–1 [Amended]

■ **Par. 2.** Section 1.367(a)–1 is amended by removing the language “section 936(h)(3)(B)” in paragraphs (d)(5) and (6) and adding the language “section 367(d)(4)” in its place.

■ **Par. 3.** Section 1.367(d)–1 is amended by:

- a. Removing reserved paragraphs (c)(1) through (2).
- b. Adding paragraph (c) heading and paragraphs (c)(1) and (2).
- c. Removing reserved paragraphs (c)(4) through (g)(2) (introductory text).
- d. Adding paragraphs (c)(4) and (d) through (f).
- e. Removing paragraph (g)(2)(i), reserved paragraphs (g)(2)(ii) through (iii)(D), paragraph (g)(2)(iii)(E), and reserved paragraph (g)(2)(iii) undesignated concluding paragraph.
- f. Adding paragraph (g) heading and paragraphs (g)(1) and (2).
- g. Removing reserved paragraphs (g)(4) through (i).
- h. Adding paragraphs (g)(4) through (6), (h), and (i).
- i. Revising paragraph (j).

The additions and revision read as follows:

§ 1.367(d)–1 Transfers of intangible property to foreign corporations.

* * * * *

(c) *Deemed payments upon transfer of intangible property to foreign*

corporation—(1) *In general.* For further guidance, see § 1.367(d)–1T(c)(1).

(2) *Required adjustments.* For further guidance, see § 1.367(d)–1T(c)(2) introductory text and (c)(2)(i).

(i) [Reserved]

(ii) The deemed payment is treated as an allowable deduction (whether or not that amount is paid) of the transferee foreign corporation properly allocated and apportioned to the appropriate classes of gross income in accordance with §§ 1.882–4(b)(1), 1.951A–2(c)(3), 1.954–1(c), and 1.960–1(c) and (d), as applicable.

* * * * *

(4) *Blocked income.* For further guidance, see § 1.367(d)–1T(c)(4).

(d) *Subsequent transfer of stock of transferee corporation to unrelated person.* For further guidance, see § 1.367(d)–1T(d).

(e) *Subsequent transfer of stock of transferee foreign corporation to related person—*(1) *Transfer to related U.S. person treated as disposition of intangible property.* For further guidance, see § 1.367(d)–1T(e)(1).

(2) *Required adjustments.* For further guidance, see § 1.367(d)–1T(e)(2) introductory text and (e)(2)(i).

(i) [Reserved]

(ii) The deemed payment is treated as an allowable deduction (whether or not that amount is paid) of the transferee foreign corporation properly allocated and apportioned to the appropriate classes of gross income in accordance with §§ 1.882–4(b)(1), 1.951A–2(c)(3), 1.954–1(c), and 1.960–1(c) and (d), as applicable.

(iii) For further guidance, see § 1.367(d)–1T(e)(2)(iii) through (e)(4).

(iv) [Reserved]

(3) through (4) [Reserved]

(f) *Subsequent disposition of transferred intangible property by transferee foreign corporation—*(1) *In general.* For further guidance, see § 1.367(d)–1T(f)(1).

(2) *Required adjustments.* If a U.S. transferor is required to recognize gain under paragraph (f)(4)(i)(A) of this section or § 1.367(d)–1T(f)(1), then, in addition to the adjustments described in paragraph (c)(2)(ii) of this section and § 1.367(d)–1T(c)(2) with respect to the deemed payment described in § 1.367(d)–1T(f)(1)(ii)—

(i) For purposes of chapter 1 of the Code, the transferee foreign corporation reduces (but not below zero) the portion of its earnings and profits and gross income arising by reason of the subsequent disposition of the intangible property by the amount of gain recognized by the U.S. transferor under paragraph (f)(4)(i)(A) of this section or § 1.367(d)–1T(f)(1); and

(ii) The U.S. transferor may establish an account receivable from the transferee foreign corporation equal to the amount of gain recognized under paragraph (f)(4)(i)(A) of this section or § 1.367(d)–1T(f)(1) in accordance with § 1.367(d)–1T(g)(1).

(3) *Subsequent transfer of intangible property to related person.* Except as provided in paragraph (f)(4)(i)(B) of this section, a U.S. person's requirement to recognize income under § 1.367(d)–1T(c) or (e) is not affected by the transferee foreign corporation's subsequent disposition of the transferred intangible property to a related person. For purposes of any required adjustments, and of any accounts receivable created under § 1.367(d)–1T(g)(1), the related person that receives the intangible property is treated as the transferee foreign corporation.

(4) *Subsequent transfer of intangible property to qualified domestic person—*

(i) *In general.* Except as provided in paragraph (f)(4)(v) of this section, if a U.S. person transfers intangible property subject to section 367(d) and the rules of this section and § 1.367(d)–1T to a foreign corporation in an exchange described in section 351 or 361 and, within the useful life of the intangible property, that transferee foreign corporation subsequently disposes of the intangible property to a qualified domestic person, then—

(A) The U.S. transferor of the intangible property (or any person treated as such pursuant to § 1.367(d)–1T(e)(1)) is required to recognize gain, as applicable, equal to the amount described in paragraph (f)(4)(ii) of this section; and

(B) If the U.S. transferor provides the information described in § 1.6038B–1(d)(2)(iv), then—

(1) The U.S. transferor is required to recognize a deemed payment as provided in § 1.367(d)–1T(f)(1)(ii); and

(2) The intangible property is no longer subject to section 367(d), this section, or § 1.367(d)–1T after applying paragraphs (f)(4)(i)(A) and (f)(4)(i)(B)(1) of this section.

(ii) *Gain recognition for U.S. transferor.* The amount of gain a U.S. transferor must recognize under paragraph (f)(4)(i)(A) of this section is determined as follows—

(A) If the intangible property is transferred basis property (as defined in section 7701(a)(43)) by reason of the subsequent disposition (determined without regard to section 367(d), this section, and § 1.367(d)–1T), the amount of gain, if any, the transferee foreign corporation would recognize if its adjusted basis in the intangible property

were equal to the U.S. transferor's former adjusted basis in the property; or

(B) If the intangible property is not transferred basis property by reason of the subsequent disposition (determined without regard to section 367(d), this section, and § 1.367(d)–1T), the excess, if any, of the fair market value of the intangible property on the date of the subsequent disposition over the U.S. transferor's former adjusted basis in that property.

(iii) *Qualified domestic person.* For purposes of this paragraph (f)(4), a *qualified domestic person* means—

(A) The U.S. transferor that initially transferred intangible property subject to section 367(d);

(B) A U.S. person treated as a U.S. transferor under § 1.367(d)–1T(e)(1), provided such person is an individual or a corporation other than a corporation exempt from tax under section 501(a), a regulated investment company (as defined in section 851(a)), a real estate investment trust (as defined in section 856(a)), a DISC (as defined in section 992(a)(1)), or an S corporation (as defined in section 1361(a));

(C) A U.S. person that is an individual related, within the meaning of paragraph (h)(2)(ii) of this section and § 1.367(d)–1T(h), to the person described in paragraph (f)(4)(iii)(A) or (B) of this section; or

(D) A U.S. person that is a corporation related, within the meaning of paragraph (h)(2)(ii) of this section and § 1.367(d)–1T(h), to the person described in paragraph (f)(4)(iii)(A) or (B) of this section, other than a corporation exempt from tax under section 501(a), a regulated investment company (as defined in section 851(a)), a real estate investment trust (as defined in section 856(a)), a DISC (as defined in section 992(a)(1)), or an S corporation (as defined in section 1361(a)).

(iv) *Qualified domestic person's basis in the intangible property.* The qualified domestic person's adjusted basis in the intangible property is—

(A) In the case of a subsequent disposition of intangible property described in paragraph (f)(4)(ii)(A) of this section, and subject to any applicable limitations that may apply under the Code, the lesser of the U.S. transferor's former adjusted basis in the intangible property or the transferee foreign corporation's adjusted basis in the intangible property (as determined immediately before the subsequent disposition), in each case increased by the greater of the amount of gain (if any) described in paragraph (f)(4)(ii)(A) of this section and recognized by the U.S. transferor or the amount of gain (if any) recognized by the transferee foreign

corporation as to the intangible property by reason of the subsequent disposition; or

(B) In the case of a subsequent disposition of intangible property described in paragraph (f)(4)(ii)(B) of this section, the fair market value of the intangible property (as determined on the date of the subsequent disposition).

(v) *Special rule for related transactions.* If the transferee foreign corporation subsequently disposes of the transferred intangible property to a person that would, absent this paragraph (f)(4)(v), be a qualified domestic person (initial transferee) and, as part of a series of related transactions, the intangible property is subsequently disposed of to any other person, including by reason of multiple dispositions, then the initial transferee is treated as a qualified domestic person only if the ultimate recipient of the intangible property is a qualified domestic person. See paragraphs (f)(6)(ii)(D) and (E) of this section (*Examples 4 and 5*) for illustrations of the application of this paragraph (f)(4)(v).

(5) *Relief for certain failures to comply.* This paragraph (f)(5) provides relief if paragraph (f)(4)(i)(B)(2) of this section would apply but for the U.S. transferor's failure to provide the information required by paragraph (f)(4)(i)(B) of this section (a "failure to comply"). When a failure to comply occurs, the subsequent disposition of the transferred intangible property is generally subject to paragraphs (f)(3) and (f)(4)(i)(A) of this section. Nevertheless, a failure to comply is deemed not to have occurred (regardless of whether the U.S. transferor continued to include amounts in gross income under § 1.367(d)–1T(c) or (e) after the subsequent disposition), and the requirements of paragraph (f)(4)(i)(B) of this section are treated as satisfied as of the date of the subsequent disposition if—

(i) Promptly after the U.S. transferor becomes aware of the failure, the U.S. transferor provides such information and provides a reasonable explanation for its failure to comply to the Director of Field Operations, Cross Border Activities Practice Area of Large Business & International (or any successor to the roles and responsibilities of such position, as appropriate), by eFax at (855) 582–4842 (or as otherwise directed on *irs.gov*), or, if any taxable year of the U.S. transferor is under examination when the discovery is made, to the Internal Revenue Service personnel conducting the examination;

(ii) The U.S. transferor timely files an amended return for the taxable year in which the subsequent disposition occurred (and, if applicable, for each taxable year starting with the taxable year immediately after the taxable year in which the subsequent disposition occurred and ending with the taxable year in which the U.S. transferor seeks relief under this paragraph (f)(5)) that includes the information required by paragraph (f)(4)(i)(B) of this section; and

(iii) If any taxable year of the U.S. transferor is under examination when an amended return is filed, the U.S. transferor provides a copy of the amended return (or, if applicable, amended returns) to the Internal Revenue Service personnel conducting the examination.

(6) *Examples—(i) Assumed facts.* For purposes of the examples in paragraph (f)(6)(ii) of this section, and except where otherwise indicated, the following facts are assumed.

(A) USP and USS are domestic corporations that each use a calendar taxable year.

(B) TFC is a foreign corporation whose functional currency is the U.S. dollar.

(C) In year 1, USP transfers intangible property, as defined in section 367(d)(4), with a \$0 adjusted basis, to TFC in a section 351 exchange (the transferred IP), and such transfer is subject to section 367(d).

(D) Each annual inclusion (including any amount described in § 1.367(d)–1T(f)(1)(ii)) is taken into account under section 367(d)(2)(A)(ii)(I) and § 1.367(d)–1T(c)(1).

(E) Any subsequent transfer or disposition of stock of TFC or the transferred IP occurs within the useful life of the transferred IP.

(F) All transactions are respected under general principles of tax law.

(ii) *Examples.* The following examples illustrate the application of paragraph (f)(4) of this section and other paragraphs of this section that relate to paragraph (f)(4).

(A) *Example 1: Complete liquidation of transferee foreign corporation into a qualified domestic person—(1) Facts.* In year 2, USP transfers all the stock of TFC to USS, a related person within the meaning of § 1.367(d)–1T(h) and paragraph (h)(2)(ii) of this section, in a section 351 exchange to which § 1.367(d)–1T(e)(1) applies (the year 2 transfer). In year 3, TFC distributes all its property (including the transferred IP) to USS pursuant to a complete liquidation to which sections 332 and 337 apply (the year 3 liquidation). The all earnings and profits amount determined under § 1.367(b)–2(d) with

respect to the stock of TFC held by USS is \$0. The information described in § 1.6038B–1(d)(2) is provided by USS for the taxable year in which the year 3 liquidation occurs.

(2) *Analysis—(i) The year 2 transfer.* Because the year 2 transfer involves a transfer of all the stock of TFC by USP (the initial U.S. transferor) to a related U.S. person (USS), under § 1.367(d)–1T(e)(1)(i) USS (a successor U.S. transferor) is treated as receiving the right to receive a proportionate share of the contingent annual payments that USP would have otherwise taken into account under § 1.367(d)–1T(c). As determined under § 1.367(d)–1T(e)(4), USS's proportionate share of such payments is 100 percent. Accordingly, USS will annually include in its gross income the full amount of each of the annual payments that USP would otherwise have taken into account under § 1.367(d)–1T(c) over the useful life of the transferred IP, and USP will not recognize any gain upon the year 2 transfer. See § 1.367(d)–1T(e)(1)(ii) and (iii).

(ii) *The year 3 liquidation.* The year 3 liquidation results in a subsequent disposition of the transferred IP to USS. USS, a U.S. person treated as the U.S. transferor pursuant to § 1.367(d)–1T(e)(1), is a qualified domestic person within the meaning of paragraph (f)(4)(iii) of this section. Pursuant to paragraph (f)(4)(i)(A) of this section, USS must recognize the amount of gain described in paragraph (f)(4)(ii) of this section. Because the year 3 liquidation is a complete liquidation to which sections 332 and 337 apply, the intangible property is transferred basis property (as defined in section 7701(a)(43) and determined without regard to section 367(d), this section, and § 1.367(d)–1T), and therefore paragraph (f)(4)(ii)(A) of this section applies to determine the amount of any gain USS must recognize. Because TFC does not recognize gain with respect to the transferred IP (regardless of the adjusted basis in the intangible property) by reason of the year 3 liquidation, the amount of gain described in paragraph (f)(4)(ii)(A) of this section is \$0. Accordingly, USS does not recognize gain pursuant to paragraph (f)(4)(i)(A) of this section by reason of the year 3 liquidation. Additionally, because USS provides the information described in § 1.6038B–1(d)(2), paragraph (f)(4)(i)(B) of this section applies to the year 3 liquidation. USS therefore recognizes a deemed payment representing the part of USS's taxable year during which TFC held the transferred IP pursuant to paragraph (f)(4)(i)(B)(1) of this section, and the

required adjustments described in paragraph (c)(2)(ii) of this section and § 1.367(d)–1T(c)(2)(i) apply as to the deemed payment. Also, because USS does not recognize gain pursuant to paragraph (f)(4)(i)(A) of this section, the required adjustments described in paragraph (f)(2) of this section do not apply. Pursuant to paragraph (f)(4)(i)(B)(2) of this section, after taking the deemed payment into account, the transferred IP is no longer subject to section 367(d), this section, and § 1.367(d)–1T. Finally, pursuant to paragraph (f)(4)(iv)(A) of this section, USS's adjusted basis in the transferred IP is \$0, which is equal to USP's former adjusted basis in the transferred IP (\$0), increased by the greater of the amount of gain recognized by USS under paragraph (f)(4)(i)(A) of this section (\$0) or the amount of gain recognized by TFC upon the year 3 liquidation (\$0).

(B) *Example 2: Taxable distribution of the transferred intangible property to a qualified domestic person—(1) Facts.* The facts are the same as in paragraph (f)(6)(ii)(A) of this section (*Example 1*), except that, instead of in year 3 TFC distributing all its property to USS pursuant to a complete liquidation, in year 3 TFC distributes the transferred IP to USS in a distribution described in section 311(b) when the fair market value of the transferred IP is \$100x (the year 3 distribution). TFC's adjusted basis in the transferred IP immediately before the distribution is \$0.

(2) *Analysis.* The consequence of the year 2 transfer is the same as described in paragraph (f)(6)(ii)(A)(2)(i) of this section (*Example 1*). Like the consequences described in paragraph (f)(6)(ii)(A)(2) of this section (*Example 1*), the year 3 distribution is a subsequent disposition of the transferred IP to USS, a qualified domestic person. Pursuant to paragraph (f)(4)(i)(A) of this section, USS must recognize the amount of gain described in paragraph (f)(4)(ii) of this section. Because the year 3 distribution is described in section 311(b) the intangible property is not transferred basis property (as defined in section 7701(a)(43) and determined without regard to section 367(d), this section, and § 1.367(d)–1T), and therefore USS must recognize \$100x gain under paragraph (f)(4)(ii)(B) of this section. The \$100x gain amount equals the excess of the fair market value of the transferred IP on the date of the year 3 distribution (\$100x) over USP's former adjusted basis in the property (\$0). TFC, because of USS's gain recognition under paragraph (f)(4)(i)(A) of this section, reduces (but not below zero) the portion of its earnings and profits and gross

income arising by reason of the year 3 distribution by the amount of such gain under paragraph (f)(2)(i) of this section. Specifically, because the year 3 distribution requires USS to recognize \$100x of gain, TFC reduces the portion of its earnings and profits and gross income that arise by reason of the year 3 distribution, which is \$100x (the excess of the fair market value of the transferred IP (\$100x) over TFC's adjusted basis in the transferred IP (\$0)), by \$100x (the amount of gain USS recognizes pursuant to paragraph (f)(4)(i)(A) of this section). As a result, after taking into account the reduction, TFC has no earnings and profits or gross income that arise by reason of the year 3 distribution. Furthermore, USS may establish an account receivable from TFC equal to \$100x under paragraph (f)(2)(ii) of this section. Additionally, and as described in paragraph (f)(6)(ii)(A)(2) of this section (*Example 1*), pursuant to paragraph (f)(4)(i)(B)(1) of this section, USS recognizes a deemed payment for the portion of USS's taxable year during which TFC held the transferred IP, and the required adjustments described in paragraph (c)(2)(ii) of this section and § 1.367(d)–1T(c)(2) apply to this deemed payment. After taking these consequences into account, pursuant to paragraph (f)(4)(i)(B)(2) of this section, the transferred IP is no longer subject to section 367(d), this section, and § 1.367(d)–1T. Finally, pursuant to paragraph (f)(4)(iv)(B) of this section, USS's adjusted basis in the transferred IP is \$100x, which is the fair market value of the transferred IP on the date of the year 3 distribution.

(C) *Example 3: Qualified domestic person's basis in intangible property when intangible property is repatriated in an exchange described in section 351(b)—(1) Facts.* The facts are the same as in paragraph (f)(6)(ii)(A) of this section (*Example 1*), except that the transfer of stock of TFC to USS in year 2 does not occur and instead of the year 3 liquidation, in year 3 TFC transfers the intangible property to USS (a qualified domestic person as defined in paragraph (f)(4)(iii) of this section) in an exchange described in section 351(b) pursuant to which TFC recognizes \$50x of gain and USP recognizes \$50x of gain under paragraph (f)(4)(i)(A) of this section (the year 3 exchange), which amount will reduce TFC's earnings and profits and gross income by \$50x under paragraph (f)(2)(i) of this section.

(2) *Analysis.* Pursuant to paragraph (f)(4)(iv)(A) of this section, USS's adjusted basis in the intangible property is \$50x, which is the amount equal to the lesser of USP's former adjusted basis

in the property (\$0) or TFC's adjusted basis in the property (\$0), increased by the greater of the amount of gain recognized by USP under paragraph (f)(4)(i)(A) of this section (\$50x) or the amount of gain recognized by TFC upon the year 3 exchange (\$50x).

(D) *Example 4: Repatriation as part of a series of related transactions culminating in transfer to a foreign corporation—(1) Facts.* The facts are the same as in paragraph (f)(6)(ii)(A)(1) of this section (*Example 1*), except that the year 3 liquidation occurs as part of a series of related transactions pursuant to which USS transfers the transferred IP that it receives from TFC to a related foreign corporation (FC1) in exchange for stock in FC1.

(2) *Analysis.* Because the year 3 liquidation occurs as part of a series of related transactions pursuant to which the transferred IP is ultimately contributed to a FC1, a foreign corporation, and because a foreign corporation is not a qualified domestic person pursuant to paragraph (f)(4)(iii) of this section, then, under paragraph (f)(4)(v) of this section, the year 3 liquidation is not treated as a subsequent disposition described in paragraph (f)(4)(i) of this section, but is instead treated as a subsequent disposition described in paragraph (f)(3) of this section.

(E) *Example 5: Repatriation as part of a series of related transactions culminating in transfer to a qualified domestic person—(1) Facts.* The facts are the same as in paragraph (f)(6)(ii)(B)(1) of this section (*Example 2*), except that the year 3 distribution occurs as part of a series of related transactions pursuant to which USS disposes of the transferred IP that it receives from TFC to USP.

(2) *Analysis.* Because the year 3 distribution occurs as part of a series of related transactions pursuant to which the transferred IP is distributed to USP, and because USP is a qualified domestic person pursuant to paragraph (f)(4)(iii) of this section, paragraph (f)(4)(v) of this section does not prevent paragraph (f)(4)(i) of this section from applying to the year 3 distribution. Accordingly, the consequences under section 367(d) of the year 3 distribution are the same as those described in paragraph (f)(6)(ii)(B)(2) of this section (*Example 2*), and the consequences of the subsequent disposition of the transferred IP by USS to USP are determined after applying paragraph (f)(4) of this section to the transfer of the transferred IP by TFC to USS.

(g) *Special rules—(1) Establishment of accounts receivable.* For further guidance, see § 1.367(d)–1T(g)(1).

(2) *Election to treat transfer as sale.* For further guidance, see § 1.367(d)–1T(g)(2) introductory text.

(i) The intangible property transferred constitutes an operating intangible, as defined in § 1.367(a)–1(d)(6).

(ii) For further guidance, see § 1.367–1T(g)(2)(ii) through (g)(2)(iii)(D).

(iii)(A) through (D) [Reserved]

(E) The transferred intangible property will be used in the active conduct of a trade or business outside of the United States within the meaning of § 1.367(a)–2 and will not be used in connection with the manufacture or sale of products in or for use or consumption in the United States.

(F) For further guidance, see § 1.367(d)–1T(g)(2)(iii)(F).

* * * * *

(4) *Coordination with section 482.* For further guidance, see § 1.367(d)–1T(g)(4).

(5) *Determination of fair market value.* For further guidance, see § 1.367(d)–1T(g)(5).

(6) *Anti-abuse rule.* For further guidance, see § 1.367(d)–1T(g)(6).

(h) *Related person.* For further guidance, see § 1.367(d)–1T(h) introductory text through (h)(1).

(1) [Reserved]

(2) For further guidance, see § 1.367(d)–1T(h)(2) introductory text and (h)(2)(i).

(i) [Reserved]

(ii) Section 1563 applies (for purposes of section 267(f)) without regard to section 1563(b)(2).

(i) *Effective date.* For further guidance, see § 1.367(d)–1T(i).

(j) *Applicability dates—(1) In general.* This section applies to transfers occurring on or after September 14, 2015, and to transfers occurring before September 14, 2015, resulting from entity classification elections made under § 301.7701–3 of this chapter that are filed on or after September 14, 2015. For transfers occurring before this section is applicable, see § 1.367(d)–1T as contained in 26 CFR part 1 revised as of April 1, 2016.

(2) *Certain subsequent dispositions of intangible property.* Paragraphs (c)(2)(ii), (e)(2)(ii), (f)(2) through (5), and (h)(2)(ii) of this section apply to subsequent dispositions of intangible property occurring on or after October 10, 2024. For subsequent dispositions of intangible property occurring before October 10, 2024, see § 1.367(d)–1T as contained in 26 CFR part 1 revised as of April 1, 2022.

■ **Par. 4.** Section 1.367(d)–1T is amended by:

■ a. Revising paragraph (c)(2)(ii).

■ b. Removing the undesignated paragraph following paragraph (c)(2)(ii).

■ d. Revising paragraphs (e)(2)(ii) and (f)(2).

■ e. Removing and reserving paragraph (f)(3) and adding reserved paragraphs (f)(4) through (6).

■ f. Designating the undesignated paragraph following paragraph (g)(2)(iii)(E) as paragraph (g)(2)(iii)(F).

■ g. Revising paragraph (h)(2)(ii).

The revisions read as follows:

§ 1.367(d)–1T Transfers of intangible property to foreign corporations (temporary).

* * * * *

(c) * * *

(2) * * *

(ii) For further guidance, see

§ 1.367(d)–1(c)(2)(ii).

* * * * *

(e) * * *

(2) * * *

(ii) For further guidance, see

§ 1.367(d)–1(e)(2)(ii);

* * * * *

(f) * * *

(2) *Required adjustments.* For further guidance, see § 1.367(d)–1(f)(2) through (6).

(3) through (6) [Reserved]

* * * * *

(h) * * *

(2) * * *

(ii) For further guidance, see

§ 1.367(d)–1(h)(2)(ii).

* * * * *

§ 1.367(e)–2 [Amended]

■ **Par. 5.** Section 1.367(e)–2 is amended by removing the language “section 936(h)(3)(B)” in the last sentence of paragraph (b)(2)(i)(B) and adding the language “section 367(d)(4)” in its place.

■ **Par. 6.** Section 1.904–4 is amended by adding paragraph (f)(2)(vi)(D)(4) and revising paragraph (q)(3) to read as follows:

§ 1.904–4 Separate application of section 904 with respect to certain categories of income.

* * * * *

(f) * * *

(2) * * *

(vi) * * *

(D) * * *

(4) *Multiple transfers of intangible property.* If the same intangible property is transferred in a series of transfers described in paragraph (f)(2)(vi)(D)(1) of this section, each successive transfer is separately subject to the provisions of paragraph (f)(2)(vi)(D)(1) and will not terminate or otherwise affect the application of paragraph (f)(2)(vi)(D)(1) to a prior transfer described in paragraph (f)(2)(vi)(D)(1).

* * * * *

(q) * * *

(3) Except as provided in the following sentence, paragraph (f) of this section applies to taxable years that begin after December 31, 2019, and end on or after November 2, 2020. Paragraph (f)(2)(vi)(D)(4) of this section applies to taxable years that begin on or after October 10, 2024.

■ **Par. 7.** Section 1.951A–2 is amended by revising paragraph (c)(2) to read as follows:

§ 1.951A–2 Tested income and tested loss.

* * * * *

(c) * * *

(2) *Determination of gross income and allowable deductions.* For purposes of determining tested income and tested loss, the gross income and allowable deductions of a controlled foreign corporation for a CFC inclusion year are determined under the rules of § 1.952–2 for determining the subpart F income (as defined in section 952) of the controlled foreign corporation, except, for a controlled foreign corporation which is engaged in the business of reinsuring or issuing insurance or annuity contracts and which, if it were a domestic corporation engaged only in such business, would be taxable as an insurance company to which subchapter L of chapter 1 of the Code applies, the text “the principles of §§ 1.953–4 and 1.953–5” means “the rules of sections 953 and 954(i)” in § 1.952–2(b)(2).

* * * * *

■ **Par. 8.** Section 1.951A–7 is amended by adding a paragraph (e) to read as follows:

§ 1.951A–7 Applicability dates.

* * * * *

(e) *Determination of gross income and allowable deductions.* Section 1.951A–2(c)(2) applies to taxable years of foreign corporations ending on or after October 10, 2024, and to taxable years of United States shareholders in which or with which such taxable years end. For taxable years of foreign corporations ending before October 10, 2024, and to taxable years of United States shareholders in which or with which such taxable years end, see § 1.951A–2(c)(2)(i) and (ii) as contained in 26 CFR part 1, revised as of April 1, 2022.

■ **Par. 9.** Section 1.6038B–1 is amended by:

■ a. Removing reserved paragraphs (d)(1) through (1)(iii).

■ b. Adding paragraphs (d) heading and (d)(1) introductory text and reserved paragraphs (d)(1)(i) through (iii).

■ c. Removing reserved paragraphs (d)(1)(viii) through (d)(2).

■ d. Adding paragraphs (d)(1)(viii), (d)(2), and (g)(8).

The additions read as follows:

§ 1.6038B–1 Reporting of certain transfers to foreign corporations.

* * * * *

(d) *Transfers subject to section 367(d)*—(1) *Initial transfer*. For further guidance, see § 1.6038B–1T(d)(1) introductory text through (d)(1)(iii).

(i) through (iii) [Reserved]

* * * * *

(viii) *Other intangibles*. For further guidance, see § 1.6038B–1T(d)(1)(viii).

(2) *Subsequent transfers*. For additional, see § 1.6038B–1T(d)(2) introductory text through (d)(2)(ii).

(i) through (ii) [Reserved]

(iii) *Subsequent transfer*. Except for a subsequent transfer described in paragraph (d)(2)(iv) of this section, provide the following information concerning the subsequent transfer:

(A) For further guidance, see

§ 1.6038B–1T(d)(2)(iii)(A) through (C).

(B) through (C) [Reserved]

(iv) *Subsequent transfer of intangible property to a qualified domestic person*. Provide the following information concerning a subsequent transfer of intangible property described in § 1.367(d)–1(f)(4)(i):

(A) A statement providing that § 1.367(d)–1(f)(4)(i)(B) applies to the subsequent transfer;

(B) A general description of the subsequent transfer and any wider transaction of which it forms a part, including the U.S. transferor's former adjusted basis in the intangible property and the transferee foreign corporation's adjusted basis in the intangible property (as determined immediately before the subsequent transfer), the amount and computation of any gain recognized by the U.S. transferor under § 1.367(d)–1(f)(4)(i)(A), and a description of whether the intangible property was, or is expected to be, subsequently transferred to one or more other persons (as described in § 1.367(d)–1(f)(4)(v));

(C) A description of the intangible property;

(D) A copy of the Form 926 with respect to the original transfer of the intangible property and any attachments identifying the intangible property as within the scope of section 367(d);

(E) The name, address, and taxpayer identification number of the qualified domestic person that receives the intangible property, including a statement describing the relationship between the U.S. transferor and the qualified domestic person, and, if applicable, such information regarding any other persons described in § 1.367(d)–1(f)(4)(v); and

(F) Any other information as may be prescribed by the Commissioner in

publications, forms, instructions, or other guidance.

* * * * *

(g) * * *

(8) Paragraphs (d)(2)(iii) introductory text and (d)(2)(iv) of this section apply to transfers occurring on or after October 10, 2024.

■ **Par. 10.** Section 1.6038B–1T is amended by revising paragraph (d)(2)(iii) introductory text to read as follows:

§ 1.6038B–1T Reporting of certain transactions to foreign corporations (temporary).

* * * * *

(d) * * *

(2) * * *

(iii) *Subsequent transfer*. For further guidance, see § 1.6038B–1T(d)(2)(iii) introductory text:

* * * * *

Douglas W. O'Donnell,

Deputy Commissioner.

Approved: September 23, 2024.

Aviva Aron-Dine,

Deputy Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2024–23132 Filed 10–9–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0908]

RIN 1625–AA87

Security Zone; Corpus Christi Ship Channel, Corpus Christi, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary, 500-yard radius, moving security zones within the navigable waters of the Corpus Christi Ship Channel and the La Quinta Channel. The security zone is needed to protect certain vessels carrying cargo which poses risks such that it requires an elevated level of security to protect the cargo itself and the surrounding waterway from terrorist acts, sabotage, or other subversive acts, accidents, or events of a similar nature. Entry of vessels or persons into these zones is prohibited unless specifically authorized by the Captain of the Port, Sector Corpus Christi or a designated representative.

DATES: This rule is effective from October 7, 2024 through October 17, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0908 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 about this rule, call or email Lieutenant Tim Cardenas, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–939–5130, email Tim.J.Cardenas@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port, Sector Corpus Christi
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

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard must establish this security zone by October 7, 2024, to ensure security of certain vessels and the surrounding area and lacks sufficient time to request public comments and respond to these comments before the safety zone must be established. As such, it is impracticable to publish an NPRM.

Additionally, 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**. Delaying the effective date of this rule would be contrary to the public interest because prompt action is needed to provide for the security of these vessels while they are in transit and carrying potentially dangerous cargo in need of elevated security.

III. Legal Authority and Need for Rule

The Coast Guard is issuing these security zone regulation under the authority in 46 U.S.C. 70051 and 70124. The Captain of the Port, Sector Corpus Christi (COTP) has determined that potential hazards are associated with the transit of the Motor Vessels (M/V) MARAN GAS DELPHI, TRANIANO KNUSTEN, ADAMASTOS, and HELLAS ATHINA. There is a security concern within a 500-yard radius of these vessels when they are loaded. This rule is needed to provide for the safety and security of these vessels, their cargo, and the surrounding waterway from terrorist acts, sabotage, or other subversive acts, accidents, or other events of a similar nature while the vessels are transiting within Corpus Christi, TX.

IV. Discussion of the Rule

The Coast Guard is establishing 500-yard radius, temporary, moving security zones around M/V MARAN GAS DELPHI, TRANIANO KNUSTEN, ADAMASTOS, and HELLAS ATHINA within the navigable waters of the Corpus Christi Ship Channel and the La Quinta Channel. The public will easily be able to identify these vessels because their names are clearly marked on the port and starboard bow and the stern of each vessel. The zones for these vessels will be effective from October 7, 2024, through October 17, 2024, to protect the vessels, their cargo, and the surrounding waterways from terrorist acts, sabotage, or other subversive acts, accidents, or other events of a similar nature while the vessels are traveling within the La Quinta and Corpus Christi Ship Channels. The zones will be enforced only during the time the vessels are transiting the Channels.

No vessel or person will be permitted to enter the security zone without obtaining permission from the COTP or a designated representative. 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, USCG Sector Corpus Christi (COTP) in the enforcement of the security zone. Persons or vessels desiring to enter or pass through each zone must request permission from the COTP or a designated representative on VHF-FM channel 16 or by telephone at 361-939-0450. If permission is granted, all persons and vessels must comply with the instructions of the COTP or designated representative. The COTP or

a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate for the enforcement times and dates for the security zone.

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 section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule is not subject to review by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, duration, and location of the security zone. This rule will impact a small, designated area of 500-yards around the moving vessels in the Corpus Christi Ship Channel and La Quinta Ship Channel as these vessels transit the channel over a ten-day period. Most vessels will be able to move around the security zone and therefore the impediment to the movement of other vessels will be minimal. Moreover, the rule allows other vessels to seek permission to enter or pass through each zone may request permission from the COTP or a designated representative on VHF-FM channel 16 or by telephone at 361-939-0450.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

responsibilities between the Federal Government and Indian tribes.

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 moving security zones lasting for the duration of time that the M/V MARAN GAS DELPHI, TRANIANO KNUSTEN, ADAMASTOS, HELLAS ATHINA are within the Corpus Christi Ship Channel and La Quinta Channel while loaded with cargo. It will prohibit entry within a 500-yard radius of the M/V MARAN GAS DELPHI, TRANIANO KNUSTEN, ADAMASTOS, and HELLAS ATHINA while the vessels are transiting loaded within Corpus Christi Ship Channel and La Quinta Channel. It is categorically excluded from further review under L60(a) in 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 contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C 70034, 70051; 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

- 2. Add § 165.T08–0908 to read as follows:

§ 165.T08–0908 Security Zones; Corpus Christi Ship Channel, Corpus Christi, TX.

(a) *Location.* All navigable waters encompassing a 500-yard radius around the M/V MARAN GAS DELPHI, TRANIANO KNUSTEN, ADAMASTOS, and HELLAS ATHINA, while the vessels are in the Corpus Christi Ship Channel and the La Quinta Ship Channel.

(b) *Definitions.* As used in this section, *oesignated representative* means a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Corpus Christi.

(c) *Effective period.* This section will be in effect from October 7, 2024, through October 17, 2024. This section will be enforced when any of the vessels are in the specified channels and carrying cargo.

(d) *Regulations.* (1) The general security zone regulations in subpart D of this part apply. Entry into the zone is prohibited unless authorized by the Captain of the Port Sector Corpus Christi (COTP) or a designated representative.

(2) Persons or vessels desiring to enter or pass through the zones must request permission from the COTP Sector Corpus Christi on VHF–FM channel 16 or by telephone at 361–939–0450.

(3) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate of the enforcement times and dates for this security zone.

Dated: October 4, 2024.

T.H. Bertheau,

Captain, U.S. Coast Guard, Captain of the Port, Sector Corpus Christi.

[FR Doc. 2024–23469 Filed 10–9–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 42

[Docket No. PTO–P–2023–0058]

RIN 0651–AD75

Expanding Opportunities To Appear Before the Patent Trial and Appeal Board

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Final rule.

SUMMARY: As part of its initiatives to expand access to practice before the U.S. Patent and Trademark Office (USPTO or Office), the USPTO modifies the rules regarding representation by counsel at the Patent Trial and Appeal Board (PTAB or Board) in proceedings under the Leahy-Smith America Invents Act (AIA proceedings) to: permit parties to proceed without back-up counsel upon a showing of good cause, such as a lack of resources to hire two counsel; establish a streamlined alternative procedure for recognizing counsel *pro hac vice* that is available when counsel has previously been recognized *pro hac vice* in a different PTAB proceeding; and clarify that those recognized *pro hac vice* have a duty to inform the Board of subsequent events that render inaccurate or incomplete representations they made to obtain *pro hac vice* recognition.

DATES: This rule is effective November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Scott C. Moore, Acting Senior Lead Administrative Patent Judge; or Michael P. Tierney, Vice Chief Administrative Patent Judge, both at 571–272–9797.

SUPPLEMENTARY INFORMATION:

Background

The USPTO is focused on expanding American innovation for and from all and has been examining the rules governing practice before the Office to ensure that they are properly aligned with the types of work performed by practitioners and the needs of clients. As part of this effort, the USPTO recently expanded the admission

criteria for patent bar applicants and established a separate design patent bar that is open to applicants who previously would not have been eligible to practice before the Office. See Expanding Admission Criteria for Registration To Practice in Patent Cases Before the United States Patent and Trademark Office, 88 FR 31249 (May 16, 2023); Representation of Others in Design Patent Matters Before the United States Patent and Trademark Office, 88 FR 78644 (November 16, 2023). In this final rule, the USPTO updates the rules governing practice before the Board to simplify and streamline the *pro hac vice* admission process and reduce litigation costs while ensuring parties continue to receive high quality representation.

Rules Regarding Representation by Counsel in AIA Proceedings Prior to This Final Rule

The Director of the USPTO has statutory authority to require those seeking to practice before the Office to show that they possess “the necessary qualifications to render applicants or other persons valuable service, advice, and assistance in the presentation or prosecution of their applications or other business before the Office.” 35 U.S.C. 2(b)(2)(D). Thus, courts have determined that the USPTO Director bears the primary responsibility for protecting the public from unqualified practitioners. See *Hsuan-Yeh Chang v. Kappos*, 890 F. Supp. 2d 110, 116–17 (D.D.C. 2012) (“Title 35 vests the [Director of the USPTO], not the courts, with the responsibility to protect [US]PTO proceedings from unqualified practitioners.”) (quoting *Premysler v. Lehman*, 71 F.3d 387, 389 (Fed. Cir. 1995)), *aff’d sub nom. Hsuan-Yeh Chang v. Rea*, 530 F. App’x 958 (Fed. Cir. 2013).

Pursuant to that authority and responsibility, the USPTO has promulgated regulations, administered by the Office of Enrollment and Discipline, that provide that registration to practice before the USPTO in patent matters or design patent matters requires a practitioner to demonstrate possession of “the legal, scientific, and technical qualifications necessary for [them] to render applicants valuable service.” 37 CFR 11.7(a)(2)(ii).¹ The USPTO determines whether an applicant possesses the legal qualification by administering a registration examination, which

applicants must pass before being admitted to practice. See 37 CFR 11.7(b)(ii). The USPTO sets forth guidance for establishing possession of scientific and technical qualifications in the General Requirements Bulletin for Admission to the Examination for Registration to Practice in Patent Cases before the United States Patent and Trademark Office (GRB). The GRB is available at www.uspto.gov/sites/default/files/documents/OED_GRB.pdf.

The rules that govern practice before the PTAB in AIA proceedings differ somewhat from the rules that govern other types of USPTO proceedings. In an AIA proceeding, 37 CFR 42.10(a) requires that each represented party designate a lead counsel and at least one back-up counsel. The regulation requires that lead counsel be a registered practitioner. The regulation allows non-registered practitioners to be back-up counsel upon a showing of good cause. For example, “where the lead counsel is a registered practitioner, a motion to appear *pro hac vice* by counsel who is not a registered practitioner [is] granted upon showing that counsel is an experienced litigating attorney and has an established familiarity with the subject matter at issue in the proceeding.” 37 CFR 42.10(c).

The Board typically requires that *pro hac vice* motions be filed in accordance with the “Order Authorizing Motion for *Pro Hac Vice* Admission” in *Unified Patents, Inc. v. Parallel Iron, LLC*, IPR2013–00639, Paper 7 (PTAB Oct. 15, 2013) (the *Unified Patents Order*). The *Unified Patents Order* requires that a motion for *pro hac vice* admission must:

- a. Contain a statement of facts showing there is good cause for the Board to recognize counsel *pro hac vice* during the proceeding[; and]
- b. Be accompanied by an affidavit or declaration of the individual seeking to appear attesting to the following:
 - i. Membership in good standing of the Bar of at least one State or the District of Columbia;
 - ii. No suspensions or disbarments from practice before any court or administrative body;
 - iii. No application for admission to practice before any court or administrative body ever denied;
 - iv. No sanctions or contempt citations imposed by any court or administrative body;
 - v. The individual seeking to appear has read and will comply with the Office Patent Trial Practice Guide and the Board’s Rules of Practice for Trials set forth in 37 CFR part 42;
 - vi. The individual will be subject to the USPTO Rules of Professional

Conduct set forth in 37 CFR 11.101 *et seq.* and disciplinary jurisdiction under 37 CFR 11.19(a);

vii. All other proceedings before the Office for which the individual has applied to appear *pro hac vice* in the last three years; and

viii. Familiarity with the subject matter at issue in the proceeding.

Id. at 3. If the affiant or declarant is unable to provide any of the information requested above or make any of the required statements or representations under oath, the *Unified Patents Order* requires that the individual provide a full explanation of the circumstances as part of the affidavit or declaration. *Id.* at 4.

Development of the Final Rule

On October 18, 2022, the USPTO published a request for comments in which the Office sought feedback on potential ways to expand opportunities for non-registered practitioners to appear before the PTAB. Expanding Opportunities To Appear Before the Patent Trial and Appeal Board, 87 FR 63047. The request asked several questions, including: (1) whether the USPTO should permit non-registered practitioners to appear as lead counsel in AIA proceedings, and if so, whether they should be accompanied by a registered practitioner as back-up counsel; (2) whether the USPTO should establish a new procedure by which non-registered practitioners could be admitted to practice before the PTAB; (3) what impact various proposals would have on the cost of representation; and (4) whether any changes should be implemented initially as a pilot program.

The USPTO received nine comments in response to the request. Five comments were in favor of retaining existing limits on non-registered practitioners, while four comments generally supported expanding the ways in which non-registered practitioners can participate in AIA proceedings.

The comments were split on the issue of whether non-registered practitioners should be permitted to appear as lead counsel. However, some of the comments suggested that any potential issues with allowing non-registered practitioners to serve as lead counsel could be remedied by requiring that they be accompanied by a registered practitioner as back-up counsel. Most of the comments indicated that the Office should continue to require non-registered practitioners to meet fitness-to-practice standards, but several comments agreed that it might be more efficient and less costly to the parties to establish a separate registry or

¹ Legal representation before Federal agencies is generally governed by the provisions of 5 U.S.C. 500. However, that statute provides a specific exception for representation in patent matters before the USPTO. 5 U.S.C. 500(e). See 35 U.S.C. 2(b)(2)(D) (formerly 35 U.S.C. 31).

certification procedure that would permit non-registered practitioners to avoid filing separate *pro hac vice* motions in each individual case. Several comments indicated that the rule requiring that parties retain both lead and back-up counsel might increase cost. Some of these comments asserted that the additional costs were justified to maintain the Office's high standards of representation, and others argued that the additional costs might adversely impact certain parties.

Most of the comments expressed no opinion on whether any changes should be addressed as a pilot program. Of the three comments that discussed this issue, one favored implementing any changes as a pilot program, one indicated that a pilot program would be unnecessary, and one indicated a pilot program would be unnecessary if the Office were to permit non-registered practitioners to appear as lead counsel with a registered practitioner as back-up without making other substantive changes to admissions standards.

On February 21, 2024, after careful consideration of the public input received in response to the request for comments, the USPTO published a notice of proposed rulemaking (NPRM). See Expanding Opportunities To Appear Before the Patent Trial and Appeal Board, 89 FR 13017. The NPRM granted a 90-day comment period and proposed to amend § 42.10(a) to provide that, upon a showing of good cause, the Board may permit a party to proceed without separate back-up counsel so long as lead counsel is a registered practitioner. The NPRM also proposed to amend § 42.10(c) to provide that (1) a non-registered practitioner admitted *pro hac vice* may serve as either lead or back-up counsel for a party so long as a registered practitioner is also counsel of record for that party and (2) a non-registered practitioner who was previously recognized *pro hac vice* in an AIA proceeding and not subsequently denied recognition *pro hac vice* shall be considered a PTAB-recognized practitioner and shall be eligible for automatic *pro hac vice* admission in subsequent proceedings via a simplified and expedited process that does not require the payment of a fee. The NPRM also proposed to amend § 42.10(c) to provide that those recognized *pro hac vice* have a duty to inform the Office of any developments that occur during the course of a proceeding that might have materially impacted the grant of *pro hac vice* admission had the information been presented at the time of grant.

Proposed Rule: Comments and Responses

The USPTO received a total of seven comments from five organizations and two individuals. The Office appreciates the thoughtful comments representing views from various public stakeholder communities. The comments are publicly available at the Federal eRulemaking Portal at www.regulations.gov/docket/PTO-P-2023-0058 and are addressed below.

Proposed Amendment to § 42.10(a) Permitting Parties To Proceed Without Back-Up Counsel Upon Showing of Good Cause

Five comments supported the proposal to amend § 42.10(a) to provide that upon a showing of good cause, the Board may permit a party to proceed without separate back-up counsel so long as lead counsel is a registered practitioner. Three of these comments favored the requirement that parties without back-up counsel be represented by a registered practitioner, noting that this requirement is essential to ensure quality representation and protect represented parties. One comment noted that this proposal would allow parties with limited resources to consider participating in AIA trial proceedings, thereby increasing opportunities for attorneys from small law firms and solo practitioners. Another comment suggested that the Board should go further and retain flexibility to allow a party to proceed without a registered practitioner in special circumstances. Yet another commenter supported the proposed amendments to § 42.10(a) but suggested that the requirement to retain a registered practitioner might limit the proposed rule's impact.

One comment opposed the proposed amendment to § 42.10(a), arguing that no need has been shown for such a change, that this proposal might lead to situations in which a single counsel's limited availability frustrates the progress of proceedings, and that allowing parties to proceed without back-up counsel might limit opportunities for young attorneys and under-represented members of the legal profession.

After considering the input from the comments, the USPTO is moving forward with a final rule providing that, upon a showing of good cause, the Board may permit a party to proceed without separate back-up counsel. For example, good cause may be present if a party demonstrates that it lacks the financial resources to retain both lead and back-up counsel. However, the Office notes that it would likely be

difficult for a party to demonstrate a lack of financial resources where that party has also elected to pursue litigation involving the challenged patents in other forums. The Office also notes that the good cause inquiry focuses on the needs of the party seeking relief, not the needs or preferences of counsel. Thus, for example, the fact that lead counsel is a solo practitioner who prefers to work alone would not constitute good cause for a party to proceed without separate back-up counsel.

Based on the comments and the Board's experience, the USPTO believes this rule will permit flexibility in situations in which good cause is shown, while ensuring that parties are represented by counsel having the requisite qualifications to engage in all matters before the PTAB, including in quasi-prosecution work such as claim amendments or reissue applications.² The Office believes that permitting a represented party to proceed without a registered practitioner as either lead or back-up counsel would create an unacceptable risk that the party would not receive complete advice and guidance. The Office further notes that absent a stipulation of the parties, schedule changes require approval from the Board. The Board also has authority to reconsider prior decisions granting discretionary relief, and could thus revoke permission to proceed without back-up counsel, if appropriate. Therefore, the Board has adequate authority to prevent scheduling considerations from unduly prejudicing a party.

Proposed Amendment to § 42.10(c) Permitting Non-Registered Counsel To Serve as Lead Counsel With a Registered Practitioner as Back-Up Counsel

Three comments supported the proposal to amend § 42.10(c) to permit non-registered counsel admitted *pro hac vice* to serve as lead counsel in AIA proceedings, so long as back-up counsel is a registered practitioner. However, two of these commenters indicated that they were uncertain whether allowing lead and back-up counsel to switch roles would have the desired effect of expanding opportunities at the PTAB.

Three comments opposed this proposal. These comments argued that it is important that lead counsel be qualified to discuss technical matters and quasi-prosecution matters such as claim amendments, that allowing non-

² See Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding, 84 FR 16654 (April 22, 2019).

registered counsel to serve in the lead counsel role would weaken the Office's efforts to protect the public and facilitate robust and reliable intellectual property rights, and that no need has been shown to justify amending this portion of § 42.10(c). These comments also suggested permitting non-registered counsel to serve as lead counsel would devalue the importance of a separate patent bar, increase the likelihood of sharp district court-like litigation tactics, and weaken safeguards against litigation misconduct.

In addition, two comments noted that the proposed rule omitted language in the current rule pertaining to *pro hac vice* applicants having "an established familiarity with the subject matter at issue" in a proceeding. One of these comments suggested adding this language back into the rule, and the second requested clarification regarding whether *pro hac vice* counsel must have technical familiarity with the subject matter of a proceeding, rather than just legal familiarity.

Further, the USPTO notes that it is focused on issuing and maintaining robust and reliable intellectual property rights, including robust and reliable patents resulting from amendments made in PTAB proceedings or amendments made through reissue or reexamination before, during, or after an AIA proceeding.³ Based on the Board's experience, the Office believes that requiring that lead counsel be a registered practitioner will help advance the USPTO's objectives by ensuring that parties are fully briefed on available quasi-prosecution options and have competent counsel to pursue quasi-prosecution amendments.

Based on the input from commenters and the USPTO's experience and objectives, the Office believes that a cautious approach is appropriate and will not move forward at this time with a final rule permitting non-registered counsel admitted *pro hac vice* to serve as lead counsel in AIA proceedings. Instead, the Office plans to explore a pilot project under which non-registered counsel who are admitted *pro hac vice* would be permitted to serve as lead counsel in at least some circumstances. The Office may consider moving forward at a future date with a rule permitting non-registered counsel admitted *pro hac vice* to serve as lead counsel in AIA proceedings, either in a limited or full capacity.

The USPTO further notes that the language in § 42.10(c) pertaining to *pro hac vice* applicants having an established familiarity with the subject

matter of a proceeding is used as an example and does not impose a requirement. Nevertheless, in view of the comments, the Office modifies the rule to clarify that this language refers to legal familiarity with the subject matter of a proceeding. This change will resolve the ambiguity noted above by making clear that non-registered counsel need not demonstrate technical familiarity with the subject matter of a proceeding to demonstrate good cause for *pro hac vice* recognition. It also aligns with the new streamlined *pro hac vice* procedures. Though the USPTO expects counsel to likewise have technical familiarity with the subject matter, making technical familiarity a condition of admission would indicate that technical familiarity would have to be established for each new matter.

Proposed Amendment to § 42.10(c) Streamlining Pro Hac Vice Admission Practice for Previous Pro Hac Vice Admittees

Four comments supported the proposal to amend § 42.10(c) to establish a streamlined procedure for *pro hac vice* recognition of counsel who were so recognized in a previous PTAB proceeding without requiring a fee. These comments noted that this proposal would streamline the *pro hac vice* admission process, decrease demands on the Board's scarce resources, and reduce expenses for the parties.

One comment supported streamlining the *pro hac vice* recognition process for counsel who were previously so recognized but argued that recognition for such counsel should not be automatic and that the requestor should still be required to show good cause. One commenter opposed this proposal, arguing that it would result in a single grant of a *pro hac vice* motion effectively granting permission for a non-registered attorney to appear in all future PTAB proceedings.

After considering the input from the commenters, the USPTO is moving forward with a final rule that establishes a streamlined procedure for *pro hac vice* recognition of counsel who were recognized in a previous PTAB proceeding without requiring a fee. Based on the comments and the Board's experience, the Office believes that such a rule will minimize the burden and expense of seeking *pro hac vice* recognition in subsequent cases, while ensuring compliance with fitness-to-practice standards. The Office notes that the proposed rule contains language requiring the party seeking recognition to file a declaration or affidavit affirming that all requirements set forth

by the Board for *pro hac vice* recognition are met and gives the opposing counsel an opportunity to object. These requirements, which are included in this final rule, require the requestor to demonstrate eligibility for *pro hac vice* recognition and ensure that *pro hac vice* recognition is not automatic in situations in which an opposing party contends *pro hac vice* recognition is not appropriate.

Proposed Amendment to § 42.10(c) Designating Previous Pro Hac Vice Admittees as "PTAB-Recognized Practitioners"

The proposed amendment to § 42.10(c) used the term "PTAB-recognized practitioners" to refer to non-registered counsel who were previously recognized *pro hac vice* by the Board. Two comments generally supported using this terminology to refer to counsel who were previously recognized *pro hac vice*. In contrast, two other comments argued that this terminology might lead members of the public to mistakenly believe that PTAB-recognized practitioners are registered practitioners, thereby diluting the importance of the patent bar. One other comment did not have a substantive objection to the term "PTAB-recognized practitioners" but contended that this terminology is inconsistent with the definition of "practitioners" contained in § 11.1. That comment asserted that the definition of "practitioner" in § 11.1 does not encompass non-registered counsel who are admitted *pro hac vice* in Board proceedings. Thus, the commenter argued, § 42.10(c) should not use the term "PTAB-recognized practitioners" to refer to non-registered counsel who are seeking or who were granted *pro hac vice* recognition. That comment noted that the same terminology problem appears in § 42.15(e), which also uses the term "practitioners" to refer to counsel recognized *pro hac vice*. The comment suggested that §§ 42.10(c) and 42.15(e) be revised to use the term "counsel" rather than "practitioner" to refer to non-registered attorneys who are seeking or have been granted *pro hac vice* recognition. The comment further suggested that § 42.15(e), which sets forth the fee for *pro hac vice* recognition, be revised to conform with the new procedure set forth in § 42.10(c)(2) of this rule, which does not require the payment of a fee.

The USPTO notes that the observation in the above-referenced comment with respect to the use of the term "practitioner" in § 11.1 is incorrect in that "practitioner," as defined by § 11.1, encompasses non-registered counsel

³ See *supra* n 2.

who are admitted *pro hac vice* in Board proceedings. Nevertheless, based on the totality of input from commenters, the Office revises the terminology in §§ 42.10(c) and 42.15(e) to avoid using the term “practitioner” so as to minimize the likelihood a member of the public will confuse such persons with registered practitioners. This final rule uses the term “provisionally recognized PTAB attorney” to refer to non-registered counsel who are seeking or who have been granted *pro hac vice* recognition in a Board proceeding, and the terms “counsel” or “person” to refer to those seeking or who have been granted *pro hac vice* recognition. Based on input from comments, this final rule also revises § 42.15(e) to replace the term “non-registered practitioners” with “counsel who are not registered practitioners” and to conform this section with the new procedure created by § 42.10(c)(2) of this final rule, which permits *pro hac vice* recognition in certain circumstances without the payment of a fee. As discussed below, such counsel are required to explicitly agree that they are subject to the USPTO Rules of Professional Conduct set forth in §§ 11.101 *et seq.*

Proposed Amendment to § 42.10(c) Clarifying Continuing Disclosure Duties of Pro Hac Vice Admittees

Four comments supported the proposed amendment to § 42.10(c) clarifying that non-registered counsel recognized *pro hac vice* must inform the Board of subsequent developments that render materially incomplete or incorrect information that was provided in connection with a request for *pro hac vice* recognition. No comments opposed this proposal.

After considering the input from the commenters, the USPTO is moving forward with the provision clarifying that non-registered counsel recognized *pro hac vice* must inform the Board of subsequent developments that render materially incomplete or incorrect information that was provided in connection with a request for *pro hac vice* recognition. Based on the comments and the Board’s experience, the Office believes this final rule will provide useful clarification and guidance regarding the obligations of those recognized *pro hac vice*.

Changes From the Proposed Rule

In light of the comments received, this final rule makes revisions to the NPRM as follows.

In § 42.10(c)(1), the Office has dropped the proposed language that would have permitted non-registered counsel who are recognized *pro hac vice*

to serve as lead counsel in favor of moving forward with a pilot program. The final rule retains the current language of § 42.10(c) in place of the language that was proposed in the NPRM. The final rule includes two modifications to the language in § 42.10(c). First, the following heading has been added to the beginning of § 42.10(c)(1): “*Pro hac vice* recognition of a person other than a registered practitioner.” This language is similar to the heading in the proposed version of § 42.10(c)(1) and does not change the substance of the rule. Second, the term “established familiarity” has been replaced with “established legal familiarity.” This change clarifies, in response to a comment, that an established legal familiarity with the issues in a proceeding is sufficient to support a request for *pro hac vice* admission, and technical familiarity is not a stated requirement.

To conform § 42.10(c)(2) with the change discussed above, the Office has deleted language that would have permitted a non-registered attorney admitted *pro hac vice* to serve as lead counsel.

In § 42.10(c)(2) and (3), the term “PTAB-recognized practitioner” has been replaced with “provisionally recognized PTAB attorney.” This change was made in response to commenter concerns that the public might confuse “PTAB-recognized practitioners” with registered practitioners. Also, the term “non-registered practitioner” has been replaced with “counsel who is not a registered practitioner,” the term “non-registered practitioners recognized *pro hac vice*” has been replaced with “a person recognized *pro hac vice*,” and certain instances of the term “practitioner” have been replaced with the term “counsel.” These minor changes in terminology remove the use of the term “practitioner” to refer to counsel who are seeking or have been granted *pro hac vice* recognition. Notwithstanding these changes, which are being made to avoid confusion, those admitted *pro hac vice* remain “practitioners” under USPTO rules, and must explicitly agree that they are subject to the USPTO Rules of Professional Conduct set forth in §§ 11.101 *et seq.*

The final rule contains two revisions to § 42.15(e) that were not contained in the NPRM but that commenters indicated were necessary to conform this section to the revised version of § 42.10 set forth in this final rule. First, for the same reasons discussed above, the term “non-registered practitioners” in § 42.15(e) has been replaced with

“counsel who are not registered practitioners.” Second, § 42.15(e) has been revised to conform with § 42.10(c)(2) of this final rule, which provides for a new procedure for *pro hac vice* recognition that does not require a fee.

Discussion of the Final Rule

Section 42.10(a) is amended to clarify that lead counsel must be a registered practitioner and to provide that, upon a showing of good cause, the Board may permit a party to proceed without separate back-up counsel.

Section 42.10(c) is amended to clarify that an established legal familiarity with the subject matter of a proceeding is sufficient to support a request for *pro hac vice* recognition, and technical familiarity is not required. Section 42.10(c) is also amended to provide a new procedure whereby a non-registered attorney who was previously recognized *pro hac vice* in an AIA proceeding and not subsequently denied recognition *pro hac vice* shall be considered a provisionally recognized PTAB practitioner and shall be eligible for automatic *pro hac vice* admission in subsequent proceedings via a simplified and expedited process that does not require the payment of a fee. Section 42.10(c) is further amended to provide that those recognized *pro hac vice* have a duty to inform the Office of any developments that occur during the course of a proceeding that might have materially impacted the grant of *pro hac vice* admission had the information been presented at the time of grant. The terminology of § 42.10(c) is also amended to use the terms “counsel” or “person” rather than “practitioner” to refer to persons who are seeking or have been granted *pro hac vice* recognition.

Section 42.15(e) is amended to replace the term “non-registered practitioners” with the term “counsel who are not registered practitioners” and to conform with § 42.10(c)(2) of this final rule, which permits certain persons to seek *pro hac vice* recognition without the payment of a fee.

Rulemaking Requirements

A. Administrative Procedure Act: The changes in this rulemaking involve rules of agency practice and procedure and/or interpretive rules and do not require notice-and-comment rulemaking. See *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 97, 101 (2015) (explaining that interpretive rules “advise the public of the agency’s construction of the statutes and rules which it administers” and do not require notice-and-comment when issued or amended); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336–37 (Fed.

Cir. 2008) (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”); and *JEM Broadcasting Co. v. F.C.C.*, 22 F.3d 320, 328 (D.C. Cir. 1994) (explaining that rules are not legislative because they do not “foreclose effective opportunity to make one’s case on the merits”).

Nevertheless, the USPTO chose to seek public comment before implementing this rule to benefit from the public’s input.

B. Regulatory Flexibility Act: For the reasons set forth in this rulemaking, 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 changes in this final rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

This rule permits parties to proceed without back-up counsel upon a showing of good cause, creates a new streamlined procedure for recognizing counsel *pro hac vice* that is available for counsel who have previously been recognized *pro hac vice* in a different Board proceeding, and clarifies that those recognized *pro hac vice* have a duty to inform the Board if the information presented in a request for *pro hac vice* recognition is no longer accurate or complete. These changes do not limit or restrict counsel who meet current eligibility criteria to practice before the Board and would not limit or restrict the ability of parties to designate counsel of their choosing. The USPTO does not collect or maintain statistics on the size status of impacted entities, which would be required to determine the number of small entities that will be affected by the rule. However, the changes in this rule are not expected to have any material impact on otherwise regulated entities because the changes to the regulations are procedural in nature, do not impose any significant new burdens or requirements on parties or counsel, and are designed to reduce the cost and complexity of Board proceedings. Although this rule includes a new requirement to inform the Board if information submitted in a request for *pro hac vice* recognition is no longer accurate or complete, the number of impacted entities is expected to be very small, and any additional cost burden is expected to be minimal. Accordingly, the changes in this rule are expected to be of minimal additional

burden to those practicing before the Office.

For the reasons discussed above, this rulemaking will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of E.O. 12866 (Sept. 30, 1993), as amended by E.O. 14094 (Apr. 6, 2023).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, and as discussed above, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the 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 rulemaking pertains strictly to Federal agency procedures and does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under E.O. 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking 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 E.O. 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under E.O. 13211 because this rulemaking 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 E.O. 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden, as set forth in sections 3(a) and 3(b)(2) of E.O. 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under E.O. 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not affect a taking of private property or otherwise have taking implications under E.O. 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 *et seq.*), the USPTO will submit a report containing the final 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 rulemaking 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 U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not a “major rule” as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes 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 rulemaking 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 rulemaking 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 Office consider the impact of paperwork and other information collection burdens imposed on the public. This rulemaking involves information collection requirements that are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The collections of information involved in this rulemaking have been reviewed and previously approved by OMB under OMB control number 0651-0069 (Patent Review and Derivation Proceedings). Updates to this information collection that result from the final rule will be submitted to the OMB as non-substantive change requests.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information 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 42

Administrative practice and procedure, Inventions and patents, Lawyers.

For the reasons set forth in the preamble, the USPTO amends 37 CFR part 42 as follows:

PART 42—TRIAL PRACTICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

■ 1. The authority citation for part 42 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), 3, 6, 21, 23, 41, 134, 135, 143, 153, 311, 312, 314, 316, 318, 321–326, 328; Pub. L. 112–29, 125 Stat. 284; and Pub. L. 112–274, 126 Stat. 2456.

■ 2. Amend § 42.10 by revising paragraphs (a) and (c) to read as follows:

§ 42.10 Counsel.

(a) If a party is represented by counsel, the party must designate a lead

counsel and at least one back-up counsel who can conduct business on behalf of the lead counsel. Lead counsel must be a registered practitioner. The Board may permit a party to proceed without back-up counsel upon a showing of good cause. A party may show good cause by demonstrating that it lacks the financial resources to retain both lead and back-up counsel.

* * * * *

(c)(1) *Pro hac vice recognition of a person other than a registered practitioner.* The Board may recognize counsel *pro hac vice* during a proceeding upon a showing of good cause, subject to the condition that lead counsel be a registered practitioner and to any other conditions the Board may impose. For example, where the lead counsel is a registered practitioner, a motion to appear *pro hac vice* by counsel who is not a registered practitioner may be granted upon showing that counsel is an experienced litigating attorney and has an established legal familiarity with the subject matter at issue in the proceeding.

(2) *Pro hac vice recognition of provisionally recognized PTAB attorneys.* (i) Any counsel who is not a registered practitioner, who has been previously recognized *pro hac vice* in a Board proceeding, and who has not subsequently been denied permission to appear *pro hac vice* in a Board proceeding shall be considered a provisionally recognized PTAB attorney. Provisionally recognized PTAB attorneys shall be eligible for automatic *pro hac vice* admission in subsequent proceedings, subject to the following conditions.

(ii) If a party seeks to be represented in a proceeding by a provisionally recognized PTAB attorney, that party may file a notice of intent to designate a provisionally recognized PTAB attorney as back-up counsel. No fee is required for such a notice. The notice shall:

(A) Identify a registered practitioner who will serve as lead counsel, and

(B) Be accompanied by a certification in the form of a declaration or affidavit in which the provisionally recognized PTAB attorney attests to satisfying all requirements set forth by the Board for *pro hac vice* recognition of a provisionally recognized PTAB attorney and agrees to be subject to the USPTO Rules of Professional Conduct set forth in §§ 11.101 *et seq.* of this chapter and disciplinary jurisdiction under § 11.19(a) of this chapter.

(iii) Any objection shall be filed by a party within five business days after the

filing of the notice. If an objection is not filed within five business days, the provisionally recognized PTAB attorney shall be deemed admitted *pro hac vice* in that proceeding upon filing of updated mandatory notices identifying that counsel as counsel of record. If an objection is filed by a party within 5 business days, unless the Board orders otherwise within 10 business days after the objection is filed, the provisionally recognized PTAB attorney shall be deemed admitted *pro hac vice* after updated mandatory notices identifying that counsel as counsel of record are then filed.

(iv) If a provisionally recognized PTAB attorney is unable to satisfy any of the requirements set forth by the Board, or is unable to make any of the required attestations under oath, this procedure is not available, and *pro hac vice* recognition must instead be sought under the process set forth in paragraph (c)(1) of this section.

(3) *Continuing duty of persons recognized pro hac vice.* For the entire duration of any proceeding in which counsel who is not a registered practitioner is recognized *pro hac vice* pursuant to paragraph (c)(1) or (2) of this section, the counsel who is not a registered practitioner has a continuing duty to notify the Board in writing within five business days if:

(i) The counsel who is not a registered practitioner is sanctioned, cited for contempt, suspended, disbarred, or denied admission by any court or administrative agency;

(ii) The counsel who is not a registered practitioner no longer qualifies as a member in good standing of the Bar of at least one State or the District of Columbia; or

(iii) Any other event occurs that renders materially inaccurate or incomplete any representation that was made to the Board in connection with the request for *pro hac vice* recognition, provided, however, that counsel who is not a registered practitioner is not required to inform the Board of subsequent applications for *pro hac vice* recognition unless such an application is denied.

* * * * *

■ 3. Amend § 42.15 by revising paragraph (e) to read as follows:

§ 42.15 Fees.

* * * * *

(e) Fee for counsel who are not registered practitioners, and who are not seeking automatic recognition pursuant to § 42.10(c)(2), to appear *pro hac vice*

before the Patent Trial and Appeal Board: \$250.00

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2024–23319 Filed 10–9–24; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Parts 38 and 39

RIN 2900–AR82

Outer Burial Receptacles

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is revising its regulation that governs the outer burial receptacle (OBR) monetary allowance for burials in a VA national cemetery when a privately purchased OBR is used in lieu of a Government-furnished graveliner. First, VA is expanding applicability of the monetary allowance to burials in VA grant-funded State and Tribal cemeteries when a privately purchased OBR was used, or where an OBR is placed at the time of interment, at the cost of the State or Tribal organization. Second, VA is adding a provision to reimburse States and Tribal organizations for OBRs that are pre-placed as part of a new construction or expansion grant project. In addition, VA is making minor conforming revisions to its regulations governing aid for the establishment, expansion, and improvement of veterans cemeteries to clarify that VA will reimburse the cost of pre-placed OBRs separately from the grant award. These changes implement new authorities provided in the Johnny Isakson and David P. Roe, M.D. Veterans Health Care and Benefits Improvement Act of 2020. VA also is removing retroactive provisions no longer needed because the relevant time period has passed.

DATES: This rule is effective November 12, 2024.

FOR FURTHER INFORMATION CONTACT:

Michelle Myers, Management and Program Analyst, Policy and Regulatory Service, National Cemetery Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Telephone: (720) 607–0364. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On February 6, 2024, VA published a

proposed rule in the **Federal Register** at 89 FR 8126 that proposed revisions to 38 CFR 38.629 to include provision of OBRs for gravesites in State or Tribal organization cemeteries funded through VA grants. The proposed rule also proposed revisions to 38 CFR 39.50 to clarify that VA would reimburse the cost of pre-placed OBRs separately from the grant award and revisions to 38 CFR 39.122 to establish that a State or Tribal organization that seeks payment in the form of reimbursement or monetary allowance for OBRs under § 38.629 would be subject to related inspections, audits, and reporting. The public comment period ended on April 8, 2024, and VA received no comments in response to the proposed rule.

During the final rule drafting process, VA noted an unintended outcome based on the proposed language of § 38.629(e)(2), which we have addressed in this final rule. In the proposed rule, the monetary allowance for OBRs placed at the time of interment would have only been payable if a State or Tribal organization submitted a request for payment within 1 year of interment. However, with the time that has elapsed while developing this rulemaking, the 1-year limitation on filing requests for payment would have created an unintended barrier to awarding the benefit from the earliest date authorized by statute, January 5, 2023. This provision would have unintentionally prohibited the payment of the allowance for burials that occurred more than 1 year prior to the final rule becoming effective. To ensure that the payment of the monetary allowance for OBRs placed at the time of interment is payable for all eligible burials, VA has revised the provision to read: “Requests for payment under this section for burials that occur from January 5, 2023, through December 31, 2024, must be submitted by December 31, 2025. Requests for payment under this section for burials that occur on or after January 1, 2025, must be submitted within 1 year of interment.” This change accommodates the lag in publishing this rulemaking and ensures VA can provide payment for claims that could not be submitted until such time as this final rule becomes effective.

VA has also made technical changes to note the heading change to § 38.629(c) in the amendatory instructions, which was inadvertently omitted in the proposed rule, and to conform to cross-reference conventions. We added the phrase “of this chapter” after cross-references to other regulatory sections in §§ 38.629(h), 39.50(e), and 39.122(a).

Because no comments were received during the public comment period, VA made no changes to the proposed regulatory text besides the technical changes described here.

Executive Orders 12866, 13563, and 14094

Executive Order 12866 (Regulatory Planning and Review) directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 (Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Orders 12866 and 13563. The Office of Information and Regulatory Affairs has determined that this rulemaking is not a significant regulatory action under Executive Order 12866, as amended by Executive Order 14094. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This final rule will generally be small business neutral as it applies only to State and Tribal entities that have received a grant for a cemetery under 38 U.S.C. 2408. The Secretary acknowledges that some Tribal governments may be considered small entities; however, the economic impact would be entirely beneficial. This final rule will impose no mandatory requirements or costs on Tribal governments as a whole and will only affect those that are recipients of veterans cemetery grants. To the extent that small entities are affected, the impact of this final rule will be entirely beneficial as it will provide reimbursement for costs of OBRs associated with casketed burials in grant-funded cemeteries. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis

requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any 1 year. This final rule will have no such effect on State, local, and Tribal governments, or on the private sector.

Paperwork Reduction Act

This final rule includes a provision constituting a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The new collection of information requires approval by the Office of Management and Budget (OMB) and the assignment of an OMB Control Number. Accordingly, under 44 U.S.C. 3507(d), VA submitted a copy of this rulemaking to OMB for review and approval. VA received no comments on the new collection of information.

An OMB Control Number of 2900–0941 has been assigned to the new collection of information associated with this final rule. Assignment of this OMB control number is not an approval

to conduct or sponsor an information collection under the Paperwork Reduction Act of 1995. In accordance with 5 CFR part 1320, the new collection of information associated with this rulemaking is not approved by OMB at this time. OMB’s approval of the new collection of information will occur within 30 days after the final rulemaking publishes. If OMB does not approve the new collection of information as requested, VA will immediately remove the provision containing a new collection of information or take such other action as is directed by OMB.

The new collection of information associated with this rulemaking contained in 38 CFR 38.629 is described immediately following this paragraph.

Title: Request for Payment of Monetary Allowance for Outer Burial Receptacles.

OMB Control No.: 2900–0941.

CFR Provision: 38 CFR 38.629.

Summary of collection of information: The new collection of information in revised 38 CFR 38.629 will require a State or Tribal organization to submit a request for payment of monetary allowance for OBRs placed at the time of interment, and it will require individuals to submit a request for payment of monetary allowance for a privately purchased OBR.

Description of need for information and use of information: The information will be used by the National Cemetery Administration Financial Service Center to issue payment of the OBR monetary benefit. The information will identify the claimant and the amount claimed and will be necessary to make determinations for payment and for other budget, oversight, and compliance purposes associated with administering this benefit for burials in State and Tribal organization veterans cemeteries. In addition, VA may use a summary of this information to respond to Congressional oversight inquiries.

Description of likely respondents: Primarily Veterans Cemetery Grants Program grantees that are States and Tribal Organizations. A small number of private individuals may be respondents.

Estimated number of respondents: 110 in Fiscal Year 2024.

Estimated frequency of responses: Quarterly for States and Tribal organizations that need to request payment of monetary allowance for burials where OBRs are placed at time of interment. One-time occurrence for any individual who needs to claim the monetary allowance for a privately purchased OBR.

Estimated average burden per response: 15 minutes for all respondents.

	Estimated burden hours					
	Estimated number of respondents	Estimated number of responses	Average minutes per response	Minutes		Actual number of burden hours
		(×) times	(×) times	= (Equals)	÷ by 60 =	
Monetary Allowance for Privately Purchased OBR	100	1	15	1,500		25
Monetary Allowance for OBRs Placed at Time of Interment	10	4	15	600		10
Accumulative Total	110					35

Estimated total annual reporting and recordkeeping burden: VA estimates the total annual reporting and recordkeeping burden to be 35 burden hours. Based on an estimated number of 100 respondents filing one-time claims with an average of 15 minutes for the response, and an estimated number of 10 respondents filing claims quarterly with an average of 15 minutes for the response, the total annual reporting and recordkeeping burden is estimated to be 35 hours.

Estimated cost to respondents per year: VA estimates the annual cost for all respondents to be \$1,101.80. To estimate the total information collection burden cost, VA used the May 2023 Bureau of Labor Statistics (BLS) mean hourly wage for “all occupations” of

\$31.48 per hour. This information is available at https://www.bls.gov/oes/2023/may/oes_nat.htm#00-0000. Using VA’s estimated average annual burden of 35 hours, and using a mean hourly wage of \$31.48, VA estimates the total information collection burden cost to be \$1,101.80 per year (35 burden hours × \$31.48 mean wage per hour).

Assistance Listing

The Assistance Listing numbers and titles for the programs affected by this document are 64.201, National Cemeteries; 64.203, Veterans Cemetery Grants Program; and 64.206, VA OBR Allowance Program.

Congressional Review Act

Pursuant to subtitle E of the Small Business Regulatory Enforcement

Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as not satisfying the criteria under 5 U.S.C. 804(2).

List of Subjects

38 CFR Part 38

Administrative practice and procedure, Cemeteries, Veterans.

38 CFR Part 39

Cemeteries, Grant programs—veterans, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on October 3, 2024, and

authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, VA amends 38 CFR parts 38 and 39 as set forth below:

PART 38—NATIONAL CEMETERIES OF THE DEPARTMENT OF VETERANS AFFAIRS

■ 1. The authority citation for part 38 continues to read as follows:

Authority: 38 U.S.C. 107, 501, 512, 531, 2306, 2400, 2402, 2403, 2404, 2407, 2408, 2411, 7105.

■ 2. Amend § 38.629 as follows:

- a. Revise the section heading;
- b. Revise paragraphs (b) through (d);
- c. Redesignate paragraph (e) as paragraph (f);
- d. Add new paragraph (e);
- e. Revise the heading of newly redesignated paragraph (f) and revise newly redesignated paragraphs (f)(1) introductory text and (f)(2);
- f. Remove newly redesignated (f)(3); and
- e. Add paragraphs (g) and (h).

The revisions and additions read as follows:

§ 38.629 Outer burial receptacles.

* * * * *

(b) *Purpose.* (1) This section provides for payment of a monetary allowance for an outer burial receptacle for any interment with casketed remains in a VA national cemetery where a privately purchased outer burial receptacle has been used in lieu of a Government-furnished graveliner and, for any interment on or after January 5, 2023, in a cemetery that is the subject of a grant to a State or Tribal organization under 38 U.S.C. 2408 where a privately purchased outer burial receptacle has been used.

(2) This section also provides for payment of a monetary allowance for outer burial receptacles placed at the time of interment, for burials on or after January 5, 2023, in a cemetery that is the subject of a grant awarded to a State or Tribal organization under 38 U.S.C. 2408.

(3) This section also provides for reimbursement of the cost of pre-placed outer burial receptacles that are installed as part of construction or expansion of a cemetery that is the subject of a grant awarded on or after

January 5, 2023, to a State or Tribal organization under 38 U.S.C. 2408.

(c) *Subsequent interments.* In burials where a casket already exists in a grave with or without an outer burial receptacle, subsequent placement of a second casket in an outer burial receptacle will not be permitted in the same grave unless the cemetery director determines that the already interred casket will not be damaged.

(d) *Payment of monetary allowance for privately purchased outer burial receptacles.* (1) VA will pay a monetary allowance for each casket burial in a VA national cemetery where a privately purchased outer burial receptacle was used in lieu of a Government-furnished graveliner. Payment will be made to the person identified in records contained in the National Cemetery Administration (NCA) electronic ordering system as the person who paid for the outer burial receptacle. No application is required to receive payment of this monetary allowance as the payment is processed automatically based on entry in the system.

(2) VA will pay a monetary allowance for each casket burial in a cemetery that is the subject of a grant to a State or Tribal organization under 38 U.S.C. 2408, where a privately purchased outer burial receptacle was used on or after January 5, 2023. The person who paid for the outer burial receptacle must submit a request for payment of the allowance on the appropriate VA form. The request must be verified by the cemetery director where the burial occurred.

(e) *Payment of monetary allowance for outer burial receptacles placed at time of interment.* (1) VA will pay a monetary allowance for outer burial receptacles placed at the time of interment for burials on or after January 5, 2023, in a cemetery that is the subject of a grant to a State or Tribal organization under 38 U.S.C. 2408. Such payments may be issued on a quarterly basis and will be paid to the State agency or Tribal organization.

(2) VA will pay the allowance only if a State or Tribal organization submits a request for payment on the appropriate VA form. Requests may be submitted on a quarterly basis for the total number of burials that required an outer burial receptacle in that quarter and for which a fee for the outer burial receptacle was not charged to the decedent's family or other responsible party. Requests for payment under this section for burials that occur from January 5, 2023, through December 31, 2024, must be submitted by December 31, 2025. Requests for payment under this section for burials that occur on or after January 1, 2025,

must be submitted within 1 year of interment.

(3) No payment may be made for burials where a fee for the outer burial receptacle was charged to the decedent's family or other responsible party.

(f) *Amount of the monetary allowance.* (1) The monetary allowance will be the average cost, as determined by VA, of Government-furnished graveliners, less the administrative costs incurred by VA in processing and paying the allowance.

* * * * *

(2) The amount of the allowance for each calendar year will be published in the "Notices" section of the **Federal Register**. The **Federal Register** notice will also provide, as information, the determined average cost of Government-furnished graveliners and the determined amount of the administrative costs to be deducted.

(g) *Reimbursement for pre-placed outer burial receptacles.* (1) VA will reimburse the cost of outer burial receptacles that are pre-placed as part of new construction, expansion, or improvement of a cemetery that is the subject of a grant to a State or Tribal organization under 38 U.S.C. 2408 if the grant was awarded on or after January 5, 2023. The reimbursement will be paid to the State or Tribal organization or, if designated by the State or Tribal organization representative, the State or Tribal veterans cemetery for which such project is being carried out, or to any other State or Tribal organization, agency, or instrumentality.

(2) States and Tribal organizations must submit a request for reimbursement of the cost of pre-placed outer burial receptacles using Standard Form 271, Outlay Report and Request for Reimbursement for Construction Programs, with supporting documentation. The Director of the Veterans Cemetery Grants Program must review and certify the request for payment. Funds paid under this section for pre-placed outer burial receptacles, as part of an approved establishment, expansion, and improvement project shall be used solely for payment of such outer burial receptacles. As a condition for payment, the representative of the State or Tribal organization must submit to VA an invoice reporting the cost for purchase and delivery of outer burial receptacles.

(h) *Audits.* A State or Tribal organization that seeks reimbursement for the cost of outer burial receptacles under this section will be subject to inspections, audits, and reports in accordance with § 39.122 of this chapter.

(Authority: 38 U.S.C. 2306(e))

PART 39—AID FOR THE ESTABLISHMENT, EXPANSION, AND IMPROVEMENT, OR OPERATION AND MAINTENANCE, OF VETERANS CEMETERIES

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

Authority: 38 U.S.C. 101, 501, 2408, 2411, 3765.

■ 4. Amend § 39.50 as follows:

- a. Remove the text “preplaced liners or crypts,” from paragraph (b)(2); and
- b. Add paragraph (e).

The addition reads as follows:

§ 39.50 Amount of grant.

* * * * *

(e) VA will reimburse the cost of preplaced outer burial receptacles separately in accordance with § 38.629 of this chapter.

* * * * *

■ 5. Amend § 39.122 by revising paragraph (a) to read as follows:

§ 39.122 Inspections, audits, and reports.

(a) A State or Tribal organization will allow VA inspectors and auditors to conduct inspections as necessary to ensure compliance with the provisions of this part and with provisions of § 38.629 of this chapter regarding outer burial receptacles. The State or Tribal organization will provide to VA evidence that it has met its responsibilities under the Single Audit Act of 1984.

* * * * *

[FR Doc. 2024–23438 Filed 10–9–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 9

[Docket ID FEMA–2023–0026]

RIN 1660–AB12

Updates to Floodplain Management and Protection of Wetlands Regulations To Implement the Federal Flood Risk Management Standard; Correction

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Final rule; correcting amendment.

SUMMARY: On July 11, 2024, the Federal Emergency Management Agency

(FEMA) published a final rule implementing the Federal Flood Risk Management Standard (FFRMS), updating the agency’s 8-step decision-making process for floodplain reviews by changing how FEMA defines a floodplain with respect to certain actions and how FEMA uses natural systems, ecosystem processes, and nature-based approaches when developing alternatives to locating a proposed action in the floodplain. The rule contained two errors which this document corrects.

DATES: This rule is effective October 10, 2024 and is applicable beginning September 9, 2024.

FOR FURTHER INFORMATION CONTACT:

Portia Ross, Policy and Integration Division Director, Office of Environmental Planning and Historic Preservation, Resilience, DHS/FEMA, 400 C St. SW, Suite 313, Washington, DC 20472–3020. Phone: (202) 709–0677; Email: fema-regulations@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: On July 11, 2024, at 89 FR 56929, FEMA published a final rule implementing the FFRMS. The rule contained two errors. The first error is typographical, capitalizing a word in a defined term in § 9.4 which should be lowercased. The second error is a procedural error in the instruction and text for the amendment to § 9.9. Paragraph (d) was instructed to be fully revised, but the full paragraph was not presented in the amendatory text. This document corrects both errors.

List of Subjects in 44 CFR Part 9

Floodplains, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Federal Emergency Management Agency (FEMA) is amending 44 CFR part 9 by making the following correcting amendments.

PART 9—FLOODPLAIN MANAGEMENT AND PROTECTION OF WETLANDS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 6 U.S.C. 101 *et seq.*; 42 U.S.C. 4001 *et seq.*; 42 U.S.C. 4321 *et seq.*; E.O. 11988 of May 24, 1977, 42 FR 26951, 3 CFR, 1977 Comp., p. 117; E.O. 11990 of May 24, 1977, 42 FR 26961, 3 CFR, 1977 Comp. p. 121; E.O. 13690, 80 FR 6425; E.O. 14030, 86 FR 27967.

§ 9.4 [Corrected]

■ 2. Correct § 9.4 in the definition of “0.2 Percent annual chance floodplain” by removing “Percent” and adding “percent” in its place.

■ 3. Correct § 9.9 by removing paragraphs (1) and (2) following

paragraph (c)(5) and adding paragraph (d) in their place.

The addition reads as follows:

§ 9.9 Analysis and reevaluation of practicable alternatives.

* * * * *

(d) *Action following the analysis of practicable alternatives.* (1) The Agency shall not locate the proposed action in the floodplain as established by § 9.7(c) or in a wetland if a practicable alternative exists outside the floodplain or wetland.

(2) If no practicable alternative exists outside the floodplain or wetland, in order to carry out the action the floodplain or wetland must itself be a practicable location in light of the review required in this section.

* * * * *

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–23397 Filed 10–9–24; 8:45 am]

BILLING CODE 9111–66–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 205, 212, 214, 215, and 237

[Docket DARS–2024–0001]

Defense Federal Acquisition Regulation Supplement; Technical Amendments

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule; technical amendment.

SUMMARY: DoD is amending the Defense Federal Acquisition Regulation Supplement (DFARS) to make needed editorial changes.

DATES: Effective October 10, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer D. Johnson, Defense Acquisition Regulations System, telephone 703–717–8226.

SUPPLEMENTARY INFORMATION: This final rule amends the DFARS to make needed editorial changes to add pointers to new text in DFARS Procedures, Guidance, and Information and to remove and reserve a section containing a pointer to DFARS Procedures, Guidance, and Information, which is no longer needed.

List of Subjects in 48 CFR Parts 205, 212, 214, 215, and 237

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System amends 48 CFR parts 205, 212, 214, 215, and 237 as follows:

- 1. The authority citation for 48 CFR parts 205, 212, 214, 215, and 237 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 205—PUBLICIZING CONTRACT ACTIONS

- 2. Add subpart 205.1 to read as follows:

Subpart 205.1—Dissemination of Information

Sec.
205.102 Availability of solicitations.
205.102–70 Availability of DoD solicitations.

Subpart 205.1—Dissemination of Information**205.102 Availability of solicitations.****205.102–70 Availability of DoD solicitations.**

See PGI 205.102–70 for policy and procedures related to the Solicitation Module within the Procurement Integrated Enterprise Environment.

PART 212—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

- 3. Amend section 212.203 by adding paragraph (6) to read as follows:

212.203 Procedures for solicitation, evaluation, and award.

* * * * *

(6) See the procedures at PGI 205.102–70 for use of the Solicitation Module within the Procurement Integrated Enterprise Environment.

PART 214—SEALED BIDDING

- 4. Add section 214.203 to read as follows:

214.203 Methods of soliciting bids.

See the procedures at PGI 205.102–70 for use of the Solicitation Module within the Procurement Integrated Enterprise Environment.

PART 215—CONTRACTING BY NEGOTIATION

- 5. Add section 215.205 to read as follows:

215.205 Issuing solicitations.

See the procedures at PGI 205.102–70 for use of the Solicitation Module within the Procurement Integrated Enterprise Environment.

PART 237—SERVICE CONTRACTING**237.102–77 [Removed and Reserved]**

- 6. Remove and reserve section 237.102–77.

[FR Doc. 2024–23228 Filed 10–9–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE**Defense Acquisition Regulations System****48 CFR Parts 206, 212, 252, and 270**

[Docket DARS–2024–0017]

RIN 0750–AM01

Defense Federal Acquisition Regulation Supplement: Pilot Program To Incentivize Contracting With Employee-Owned Businesses (DFARS Case 2024–D004)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement sections of the National Defense Authorization Acts for Fiscal Year 2022 and Fiscal Year 2024 that authorize DoD to establish a pilot program that allows for the noncompetitive award of certain follow-on contracts to certain employee-owned businesses.

DATES: Effective November 25, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Jeanette Snyder, telephone 703–508–7524.

SUPPLEMENTARY INFORMATION:**I. Background**

DoD published a proposed rule in the **Federal Register** at 89 FR 46831 on May 30, 2024, to implement section 874 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) as amended by section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note). Sections 874 and 872

authorize DoD to establish a pilot program that allows for the noncompetitive award of certain follow-on contracts to employee-owned businesses that meet the definition of a qualified business. Five respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

A. Summary of Significant Changes From the Proposed Rule

There are no significant changes from the proposed rule.

B. Analysis of Public Comments**1. Support for the Rule**

Comment: The respondents expressed support for the rule.

Response: DoD acknowledges the respondents' support for the rule.

2. Clarifications

Comment: One respondent recommended revising the proposed rule text at DFARS 270.X02 to clarify that a reference to Federal Acquisition Regulation (FAR) 6.302–5 is sufficient to justify a sole-source award under the pilot program. The respondent also recommended adding the following sentence to the text: “A justification that cites FAR 6.302–5, makes reference to 48 CFR 206.302–5(b)(iii), and meets the requirements of subparts 207.X03 and 207.X04 shall be considered complete and sufficient for an exception to full an open competition.” One respondent indicated that a justification and approval (J&A) that only references FAR 6.302–5 is likely to be found insufficient by audit agencies.

Response: The proposed rule text at DFARS 270.102(b) requires the contracting officer to justify the use of a sole-source contract in accordance with FAR 6.303 and 6.304 prior to conducting negotiations and to cite FAR 6.302–5, Authorized or required by statute, as the exception to full and open competitive procedures. FAR 6.303 specifies the requirements for and the content of a justification. The statute did not modify the requirements for or content of a justification; therefore, DoD cannot make the recommended change. However, the final rule text at DFARS 270–X02(b) has been amended to remove duplicative text addressed at FAR 6.303–1(a).

3. Exceptions to Implementation

Comment: Two respondents took exception to the fact that the proposed rule does not provide a process for a contractor to apply to participate in the pilot program to ensure a transparent and accessible process. One respondent indicated the inability for a contractor to apply to participate in the pilot program is overly restrictive and inconsistent with the statute.

Response: Section 874 required the Secretary of Defense to submit to the congressional defense committees an implementation plan for the pilot program. This implementation plan indicated that applications for participation in the pilot program will be submitted by contracting officers. The proposed rule text at DFARS 270.103 is consistent with the implementation plan. As such, a contractor is not able to submit an application for participation in the pilot program.

Comment: One respondent took exception to the requirement for a J&A, indicating that it is inconsistent with the statute. The respondent further indicated that such a requirement may limit the number of businesses that may participate in the pilot program, citing the fact that there are only eight businesses currently participating in the pilot program.

Response: While sections 872 and 874 authorize the use of other than competitive procedures for the award of certain contracts under this pilot program, neither waived the requirement for a J&A; therefore, a J&A is required. The Office of the Under Secretary of Defense (Acquisition and Sustainment), Defense Pricing, Contracting, and Acquisition Policy implemented section 874 via a contract policy memorandum dated November 8, 2022, and limited participation in the pilot program to nine contractors. Therefore, the requirement for a J&A has not limited participation in the pilot program.

Comment: Three respondents took exception to the proposed rule reporting requirements, while one respondent expressed support for the reporting requirements. One respondent indicated that some of the proposed reporting requirements are open-ended and subjective, which will lead to confusion as to whether the data provided by the contractor is sufficient. One respondent indicated that the proposed reporting requirements focus on challenges of employee ownership rather than performance and value and indicated that the contractor's past performance rating in the Contractor Performance

Assessment Reporting System (CPARS) would be more useful in assessing the success of the pilot program. One respondent recommended DoD develop a comprehensive plan to monitor the implementation and impact of the Employee Stock Ownership Plan (ESOP) pilot program, allowing for adjustments and improvements over time to optimize its effectiveness. One respondent stated that its member companies who participated in the original, limited pilot program found the data collection to be straightforward and to require minimal time. Another respondent indicated that DoD's estimate of 16 hours to collect and submit the data required by the clause at DFARS 252.270–70YY should be 80 to 120 hours.

Response: Section 874 required the Secretary of Defense to establish mechanisms to collect and analyze data on the pilot program for the purposes of developing and sharing best practices with leadership and the congressional defense committees. Section 874 also required the Secretary of Defense to submit to the congressional defense committees a data collection and reporting strategy for the pilot program. The information to be reported in accordance with the contract clause at DFARS 252.270–7002, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, is consistent with this strategy. This information will be submitted to DoD leadership and the congressional defense committees and may be used to determine if additional measures should be taken to assist ESOP businesses in overcoming challenges associated with their corporate structure.

Additionally, the proposed rule text at DFARS Procedures, Guidance, and Information (PGI) 270.104, paragraph(d), specifies the reporting requirements for contracting officers, which include, but are not limited to, a summary of the contractor's performance and the benefits experienced from using the pilot program. This information will be used to assess the success of the pilot program and the need for adjustments and improvements over time. In reporting the contractor's performance pursuant to DFARS PGI 270.104, the contracting officer may use information from CPARS. To minimize the time required to collect and submit the data, the reporting requirements in the clause at DFARS 252.270–7002 are amended to clarify that data regarding challenges faced due to the contractor's corporate ownership structure is only required when applicable. In addition, contractors are only required to report data collected during the period of

performance of the contract; therefore, the data should be readily available.

4. Outside the Scope of the Rule

Comment: One respondent recommended DoD establish evaluation criteria to give preference to qualified businesses during the source-selection process in lieu of limiting the pilot program to sole-source, follow-on contracts. The respondent also recommended that DoD prioritize efforts to on-ramp qualified businesses onto multiple-award contracts to create a larger pool of qualified businesses eligible for follow-on contracts under this pilot program.

Response: These comments are outside the scope of this rule. Sections 872 and 874 do not authorize DoD to establish source selection evaluation criteria to give preference to qualified businesses or to use on-ramps under the pilot program.

C. Other Changes

DFARS 270.102(b) is revised in the final rule to simplify the direction to contracting officers. The final rule revises the prescriptions for the solicitation provisions at DFARS 252.270–7000 and 252.270–7001 and the clause at DFARS 252.270–7002 to specify that they are not to be included in solicitations and contracts solely for the acquisition of commercially available off-the-shelf items. These provisions and this clause are added to the list of provisions and clauses that are not applicable to COTS items, located at DFARS 212.371. The reporting requirements are clarified in the clause at DFARS 252.270–7002.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

The two provisions and the clause at DFARS 252.270–7000, Pilot Program to Incentivize Contracting with Employee-Owned Businesses-Representation; DFARS 252.270–7001, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Certification; and DFARS 252.270–7002, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, are prescribed at DFARS 270.105 for use in solicitations and contracts for approved acquisitions under the Pilot Program to Incentivize Contracting with Employee-Owned Businesses. Consistent with the analysis that DoD provided in the proposed rule with regard to the application of the requirements of section 874 of the NDAA for FY 2022, as amended by

section 872 of the NDAA for FY 2024, DoD has decided to not apply the statutes to contracts at or below the SAT, and DoD has made the determination to apply the statutes, as implemented in the provisions and clause at 252.270–7000, 252.270–7001, and 252.270–7002, to contracts for the acquisition of commercial products excluding COTS items and for the acquisition of commercial services, as defined at Federal Acquisition Regulation 2.101.

IV. Expected Impact of the Rule

This final rule is expected to impact the Government and contractors that participate in the Pilot Program to Incentivize Contracting with Employee-Owned Businesses. This final rule is expected to incentivize and expedite the award of follow-on contracts to qualified businesses for the continued development, production, or provision of products or services previously procured by or for DoD. As a result, employee-owned businesses may benefit from additional opportunities to contract with DoD, which may benefit DoD by expanding the defense industrial base.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules Under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VII. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is summarized as follows:

This final rule is necessary to implement section 874 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) and section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note). The objective of the rule is to implement sections 874 and 872, which authorize DoD to establish a pilot program to incentivize contracting with employee-owned businesses. The pilot program provides for the use of noncompetitive procedures for certain follow-on contracts to qualified businesses. A “qualified business” is defined as an S corporation (as defined in 26 U.S.C. 1361(a)(1)) for which 100 percent of the outstanding stock is held through an employee stock ownership plan as defined in 26 U.S.C. 4975(e)(7).

There were no significant issues raised by the public comments in response to the initial regulatory flexibility analysis. One respondent took exception to the number of hours DoD estimated it would take a contractor to comply with the reporting requirement. DoD reviewed the data to be collected and modified the reporting requirement to clarify that the contractor is required to only report challenges it faced, if any. Although not specified in the DFARS text, because this is a contract clause, contractors are only required to report data collected during the period of performance of the contract.

Data from the System for Award Management (SAM) revealed there were 384,145 small entities registered in SAM as of August 2024. Data on the number of small entities that are a qualified business, as defined in the final rule, is not available.

The pilot program was implemented on November 8, 2022. To date, eight businesses are participating in the pilot, six of which are small entities. DoD cannot estimate the number of contracting officers that will submit applications for participation in the pilot program, how many applications will be approved for participation, or how many of the subsequent awards will be made to small entities. However, based on current participation, DoD expects that the pilot program will grow to approximately 16 contractors per year, of which approximately 12 may be small entities.

This final rule imposes a new reporting requirement. Not later than 30 days after the end of the period of

performance of the contract, contractors participating in the pilot program will be required to submit to the contracting officer the following information: (1) the number of years the contractor has been wholly-owned by its employee stock ownership plan; (2) the contractor’s challenges, if any, in attracting and retaining a talented workforce due to its corporate ownership structure; (3) challenges, if any, the contractor experienced that hinder its ability to contract with DoD in order to scale its technologies and capabilities due to its corporate ownership structure; and (4) challenges, if any, the contractor experienced, due to its corporate ownership structure, in obtaining capital necessary to bridge funding gaps, for example, between prototype demonstration and full-scale development. The annual reporting burden is estimated as follows: 16 respondents, with 16 total annual responses (1 response per respondent), and a total annual burden of 16 hours.

There are no known significant alternative approaches that would accomplish the stated objectives.

VIII. Paperwork Reduction Act

This final rule contains information collection requirements that have been approved by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35). This information collection requirement has been assigned OMB Control Number 0750–0012, Defense Federal Acquisition Regulation Supplement Part 270, Defense Contracting Programs—Pilot Program to Incentivize Contracting with Employee-Owned Businesses, and Related Clause.

List of Subjects in 48 CFR Parts 206, 212, 252, and 270

Government procurement.

Jennifer D. Johnson,
Editor/Publisher, Defense Acquisition
Regulations System.

Therefore, the Defense Acquisition Regulations System amends 48 CFR chapter 2 as follows as follows:

PART 206—COMPETITION REQUIREMENTS

■ 1. The authority citation for part 206 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Revise and republish section 206.302–5 to read as follows:

206.302–5 Authorized or required by statute.

(b) *Application.* Agencies may use this authority to—

(i) Acquire supplies and services from military exchange stores outside the United States for use by the armed forces outside the United States in accordance with 10 U.S.C. 2424(a) and subject to the limitations of 10 U.S.C. 2424(b). The limitations of 10 U.S.C. 2424(b)(1) and (2) do not apply to the purchase of soft drinks that are manufactured in the United States. For the purposes of 10 U.S.C. 2424, soft drinks manufactured in the United States are brand name carbonated sodas, manufactured in the United States, as evidenced by product markings.

(ii) Acquire police, fire protection, airfield operation, or other community services from local governments at military installations to be closed under the circumstances in 237.7401 (section 2907 of Fiscal Year 1994 Defense Authorization Act (Pub. L. 103–160)).

(iii) Acquire products and services under the Pilot Program to Incentivize Contracting with Employee-Owned Businesses (see subpart 270.1).

(c) *Limitations.* (i) 10 U.S.C. 4141 precludes use of this exception for awards to colleges or universities for the performance of research and development, or for the construction of any research or other facility, unless—

(A) The statute authorizing or requiring award specifically—

(1) States that the statute modifies or supersedes the provisions of 10 U.S.C. 4141;

(2) Identifies the particular college or university involved; and

(3) States that award is being made in contravention of 10 U.S.C. 4141(a); and

(B) The Secretary of Defense provides Congress written notice of intent to award. The contract cannot be awarded until 180 days have elapsed since the date Congress received the notice of intent to award. Contracting activities must submit a draft notice of intent with supporting documentation through channels to the Principal Director, Defense Pricing, Contracting, and Acquisition Policy, Office of the Under Secretary of Defense (Acquisition and Sustainment).

(ii) The limitation in paragraph (c)(i) of this section applies only if the statute authorizing or requiring award was enacted after September 30, 1989.

(iii) Subsequent statutes may provide different or additional constraints on the award of contracts to specified colleges and universities. Contracting officers should consult legal counsel on a case-by-case basis.

PART 212—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

■ 3. The authority citation for part 212 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 4. Amend section 212.301 by adding paragraph (f)(xxii) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

* * * * *

(f) * * *

(xxii) *Part 270—Defense Contracting Programs.* (A) Use the provision at 252.270–7000, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Representation, as prescribed at 270.105(a) to comply with section 874 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) and section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note).

(B) Use the provision at 252.270–7001, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Subcontracting Certification, as prescribed at 270.105(b), to comply with section 874 of the NDAA for FY 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) and section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note).

(C) Use the clause at 252.270–7002, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, as prescribed at 270.105(c), to comply with section 874 of the NDAA for FY 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) and section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note).

■ 5. Amend section 212.371 by adding paragraphs (b), (c), and (d) to read as follows:

212.371 Inapplicability of certain provisions and clauses to contracts for the acquisition of commercially available off-the-shelf items.

* * * * *

(b) 252.270–7000, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Representation.

(c) 252.270–7001, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Subcontracting Certification.

(d) 252.270–7002, Pilot Program to Incentivize Contracting with Employee-Owned Businesses.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 6. The authority citation for part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 7. Add sections 252.270–7000, 252.270–7001, and 252.270–7002 to read as follows:

* * * * *

Sec.

252.270–7000 Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Representation.

252.270–7001 Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Subcontracting Certification.

252.270–7002 Pilot Program to Incentivize Contracting with Employee-Owned Businesses.

* * * * *

252.270–7000 Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Representation.

As prescribed in 270.105(a), use the following provision:

Pilot Program To Incentivize Contracting With Employee-Owned Businesses—Representation (NOV 2024)

(a) *Definition.* As used in this provision, *qualified business* has the meaning given in the Defense Federal Acquisition Regulation Supplement 252.270–7002, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, clause of this solicitation.

(b) *Representation.* The Offeror represents that it is a qualified business. (End of provision)

252.270–7001 Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Subcontracting Certification.

As prescribed in 270.105(b), use the following provision:

Pilot Program To Incentivize Contracting With Employee-Owned Businesses—Subcontracting Certification (NOV 2024)

(a) *Definition.* As used in this provision, *qualified business* has the meaning given in the Defense Federal Acquisition Regulation Supplement 252.270–7002, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, clause of this solicitation.

(b) *Limitations on subcontracting.* The Offeror certifies that in performance of the contract it will not expend more than 50 percent of the amount paid under the contract on subcontracts unless—

(1) The subcontract is awarded to a qualified business;

(2) The contract is for products and the subcontract is for materials not available from another qualified business; or

(3) A waiver is granted.

(End of provision)

252.270–7002 Pilot Program to Incentivize Contracting with Employee-Owned Businesses.

As prescribed in 270.105(c), use the following clause:

Pilot Program To Incentivize Contracting With Employee-Owned Businesses (NOV 2024)

(a) *Definition.* As used in this clause—
Qualified business means an S corporation as defined in 26 U.S.C. 1361(a)(1) for which 100 percent of the outstanding stock is held through an employee stock ownership plan as defined in 26 U.S.C. 4975(e)(7).

(b) *Limitations on subcontracting.* In performance of the contract, the Contractor shall not expend more than 50 percent of the amount paid under the contract on subcontracts, unless—

(1) The subcontract is awarded to a qualified business;

(2) The contract is for products and the subcontract is for materials not available from another qualified business; or

(3) A waiver is granted.

(c) *Reporting requirement.* Not later than 30 days after the end of the contract period of performance, the Contractor shall submit to the Contracting Officer the following information in writing:

(1) The number of years the Contractor has been wholly-owned by its employee stock ownership plan.

(2) Challenges, if any, the Contractor experienced in attracting and retaining a talented workforce in a competitive market due to the Contractor's corporate ownership structure.

(3) Challenges, if any, the Contractor experienced that hinder its ability to contract with DoD to scale its technologies and capabilities due to the Contractor's corporate ownership structure.

(4) Challenges, if any, the Contractor experienced, due to its corporate ownership structure, in obtaining capital necessary to bridge funding gaps, for example, between prototype demonstration and full-scale development.

(End of clause)

■ 8. Add part 270 to read as follows:

PART 270—DEFENSE CONTRACTING PROGRAMS

Sec.

270.000 Scope of part.

Subpart 270.1—Pilot Program to Incentivize Contracting with Employee-Owned Businesses

270.100 Scope of subpart.

270.101 Definition.

270.102 Policy.

270.103 Limitations.

270.104 Procedures.

270.105 Solicitation provisions and contract clause.

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

270.000 Scope of part.

This part has been created to facilitate promulgation of additional DFARS coverage of defense-specific contracting programs that do not properly fall under DFARS subchapter D, Socioeconomic Programs, and neither implement nor supplement existing FAR part 19 or parts 22 through 25.

Subpart 270.1—Pilot Program to Incentivize Contracting with Employee-Owned Businesses

270.100 Scope of subpart.

(a) This subpart implements section 874 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) and section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note). Sections 874 and 872 authorize the establishment of a pilot program that allows for the noncompetitive award of certain follow-on contracts to contractors that meet the definition of a qualified business (see 270.101).

(b) The authority to award contracts under this subpart expires on December 27, 2029.

270.101 Definition.

As used in this subpart, *qualified business* means an S corporation as defined in 26 U.S.C. 1361(a)(1) for which 100 percent of the outstanding stock is held through an employee stock ownership plan as defined in 26 U.S.C. 4975(e)(7).

270.102 Policy.

(a) The contracting officer may only award one sole-source, follow-on contract to the incumbent contractor if—

(1) The contractor has represented that it is a qualified business; and

(2) The contract is for the continued development, production, or provision of products or services that are the same as or substantially similar to those

procured under the prior contract awarded to the contractor by or for DoD.

(b) The contracting officer shall justify the use of a sole-source contract in accordance with FAR 6.303 and 6.304 and cite FAR 6.302–5 as the exception to full and open competition.

270.103 Limitations.

(a) Participation in the pilot program is subject to approval by the Under Secretary of Defense (Acquisition and Sustainment), Office of the Principal Director, Defense Pricing, Contracting, and Acquisition Policy (Contract Policy). Only a contracting officer may submit an application to participate in the pilot program. See PGI 270.104(a).

(b) Contracting officers shall only award—

(1) One sole-source, follow-on contract per predecessor contract to the incumbent contractor unless waived by the head of the contracting activity, delegable to a level no lower than one level above the contracting officer;

(2) Contracts to qualified businesses that have a minimum performance rating of satisfactory for the predecessor contract in the Contractor Performance Assessment Reporting System (see FAR subpart 42.15); and

(3) Contracts to qualified businesses that have certified they will not pay more than 50 percent of the amount paid by the Government for contract performance to subcontractors that are not qualified businesses, except for subcontracts for materials not available from another qualified business when the contract is for products, unless waived by the head of the contracting activity, delegable to a level no lower than one level above the contracting officer.

270.104 Procedures.

See PGI 270.104 for procedures and information concerning the pilot program.

270.105 Solicitation provisions and contract clause.

(a) Use the provision at 252.270–7000, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Representation, in solicitations, including solicitations using FAR part 12 procedures for the acquisition of commercial products and commercial services, except for solicitations solely for the acquisition of commercially available off-the-shelf (COTS) items, that include the clause at 252.270–7002, Pilot Program to Incentivize Contracting with Employee-Owned Businesses.

(b) Unless waived in accordance with 270.103(b)(3), use the provision at 252.270–7001, Pilot Program to

Incentivize Contracting with Employee-Owned Businesses—Subcontracting Certification, in solicitations, including solicitations using FAR part 12 procedures for the acquisition of commercial products and commercial services, except for solicitations solely for the acquisition of COTS items, that include the clause at 252.270–7002, Pilot Program to Incentivize Contracting with Employee-Owned Businesses.

(c) Use the clause at 252.270–7002, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services, except for solicitations and contracts solely for the acquisition of COTS items, for approved pilot program acquisitions.

[FR Doc. 2024–23226 Filed 10–9–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 252

[Docket DARS–2024–0018]

RIN 0750–AM03

Defense Federal Acquisition Regulation Supplement: Procurement Technical Assistance Program (DFARS Case 2024–D006)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2024 that modifies certain definitions associated with the Procurement Technical Assistance Program.

DATES: Effective October 10, 2024.

FOR FURTHER INFORMATION CONTACT: Jeanette Snyder, telephone 703–508–7524.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the *Federal Register* at 89 FR 46836 on May 30, 2024, to implement section 853 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2024 (Pub. L. 118–31; 10 U.S.C. 4951). Section 853

amends the definitions of “nonprofit organization” and “business entities” at 10 U.S.C. 4951 for the Procurement Technical Assistance Program (PTAP). One respondent submitted public comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments is provided, as follows:

A. Summary of Significant Changes From the Proposed Rule

There are no significant changes from the proposed rule.

B. Analysis of Public Comments

Comment: The respondent indicated that the statement: “In addition, business entities, including corporations, associations, partnerships, limited liability companies, limited liability partnerships, consortia, not-for-profit, or other legal entities will also be able to be a cooperative agreement holder” in section IV of the proposed rule preamble is inaccurate. The respondent indicated that the term “eligible entity” refers to the entities that may be served by cooperative agreement holders. The respondent also indicated that “(as defined in 10 U.S.C. 4951)” added to DFARS clause 252.205–7000(a) is misleading, as “business entities” are the recipients of procurement technical assistance, not the providers.

Response: Subsection (1) of 10 U.S.C. 4951 defines the term “eligible entity” to mean a state, local government, nonprofit organization, and tribal organization. Subsection (5) of 10 U.S.C. 4951 defines the term “business entity” to mean a corporation, association, partnership, limited liability company, limited liability partnership, consortia, not-for-profit, or other legal entity. The statute at 10 U.S.C. 4952 specifies that the purpose of the PTAP is, in part, to increase assistance provided by DoD to “eligible entities” furnishing procurement technical assistance to “business entities”. Therefore, the referenced statement in section IV of the proposed rule preamble is inaccurate and is corrected in this final rule. However, the parenthetical “as defined in 10 U.S.C. 4951” in the contract clause at DFARS 252.205–7000, Provision of Information to Cooperative Agreement Holders, is accurate as “business entities” in this context refers to those entities that may receive assistance.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This final rule amends the clause at DFARS 252.205–7000, Provision of Information to Cooperative Agreement Holders. However, this final rule does not impose any new requirements on contracts at or below the SAT, for commercial products including COTS items, or for commercial services. The clause will continue to not apply to acquisitions at or below the SAT, and will continue to apply to acquisitions of commercial products excluding COTS items, and to acquisitions of commercial services.

IV. Expected Impact of the Rule

This final rule is expected to impact DoD contractors whose contracts include the clause at DFARS 252.205–7000. The clause requires contractors to provide cooperative agreement holders under the PTAP, upon request, with a list of the contractor’s employees or offices responsible for entering into subcontracts under defense contracts. As a result of this final rule, such contractors may be required to provide the list to different entities that are cooperative agreement holders under the PTAP.

The changes in section 853 allow any type of nonprofit organization to be a cooperative agreement holder under the PTAP. In addition, section 853 provides a definition of “business entities” to specify the entities that may receive assistance under the PTAP, including corporations, associations, partnerships, limited liability companies, limited liability partnerships, consortia, not-for-profit, or other legal entities. These changes are reflected in the revisions to the clause at DFARS 252.205–7000. As a result, there may be increases in the number of entities that become cooperative agreement holders and in the number of business entities that receive assistance under the PTAP.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of

harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VII. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is summarized as follows:

This final rule is necessary to implement section 853 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2024 (Pub. L. 118–31; 10 U.S.C. 4951). Section 853 modifies the definitions of “nonprofit organization” and “business entities” at 10 U.S.C. 4951 for the Procurement Technical Assistance Program. The objective of this rule is to implement the revised definitions in the contract clause at DFARS 252.205–7000, Provision of Information to Cooperative Agreement Holders. The clause requires contractors to provide cooperative agreement holders under the Procurement Technical Assistance Program, upon request, with a list of the contractor’s employees or offices

responsible for entering into subcontracts under defense contracts.

There were no significant issues raised by the public comments in response to the initial regulatory flexibility analysis.

According to data from the Procurement Business Intelligence Service, in the last three fiscal years, DoD awarded contracts that included the clause at 252.205–7000 to unique small entities as follows: 5,652 in fiscal year 2021, 5,127 in fiscal year 2022, and 5,663 in fiscal year 2023. This averages out to approximately 5,480 per fiscal year. Therefore, DoD estimates that the number of small entities to which this rule will apply is approximately 5,480.

This rule does not include any new reporting, recordkeeping, or other compliance requirements for small entities.

There are no known significant alternative approaches that would accomplish the stated objectives.

VIII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies to this final rule. However, these changes to the DFARS do not impose additional information collection requirements to the paperwork burden previously approved by the Office of Management and Budget (OMB) under OMB Control Number 0704–0286, entitled Defense FAR Supplement (DFARS) Part 205, Publicizing Contract Actions, and DFARS 252.205–7000, Provision of Information to Cooperative Agreement Holders.

List of Subjects in 48 CFR Part 252

Government procurement.

Jennifer D. Johnson,
Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System amends 48 CFR part 252 as follows:

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for 48 CFR part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Revise and republish section 252.205–7000 to read as follows:

252.205–7000 Provision of Information to Cooperative Agreement Holders.

As prescribed in 205.470, use the following clause:

Provision of Information to Cooperative Agreement Holders (OCT 2024)

(a) *Definition.* As used in this clause—
Cooperative agreement holder means a State or local government; a nonprofit organization; a tribal organization (as defined in section 4(c) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(l))); or an economic enterprise (as defined in section 3(e) of the Indian Financing Act of 1974 (25 U.S.C. 1452(e))) whether such economic enterprise is organized for profit or nonprofit purposes; which has an agreement with the Under Secretary of Defense for Acquisition and Sustainment to furnish procurement technical assistance to business entities (as defined in 10 U.S.C. 4951).

(b) The Contractor shall provide cooperative agreement holders, upon their request, with a list of those appropriate employees or offices responsible for entering into subcontracts under defense contracts. The list shall include the business address, telephone number, and area of responsibility of each employee or office.

(c) The Contractor need not provide the listing to a particular cooperative agreement holder more frequently than once a year.

(End of clause)

[FR Doc. 2024–23227 Filed 10–9–24; 8:45 am]

BILLING CODE 6001–FR–P

Proposed Rules

Federal Register
Vol. 89, No. 197
Thursday, October 10, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 982

[Doc. No. AMS–SC–24–0040]

Hazelnuts Grown in Oregon and Washington; Continuance Referendum

AGENCY: Agricultural Marketing Service, USDA.
ACTION: Referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible Oregon and Washington hazelnut growers to determine whether they favor continuance of the marketing order regulating the handling of hazelnuts grown in Oregon and Washington.

DATES: The referendum will be conducted from October 28 through November 18, 2024. Only current hazelnut growers who have grown hazelnuts within the designated production area during the period July 1, 2023, through June 30, 2024, are eligible to vote in this referendum.

ADDRESSES: Copies of the marketing order may be obtained from the office of the referendum agents at 1220 SW 3rd Avenue, Suite 305, Portland, Oregon 97212; Telephone: (503) 326–2724; or the Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–8085; or on the internet <https://www.ecfr.gov/current/title-7/subtitle-B/chapter-IX/part-982>.

FOR FURTHER INFORMATION CONTACT: Virginia Tjemsland or Barry Broadbent, Northwest Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA, 1220 SW 3rd Avenue, Suite 305, Portland, Oregon 97212; Telephone: (503) 326–2724, or Email: virginia.l.tjemsland@usda.gov or barry.broadbent@usda.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Marketing Order No. 982, as amended (7 CFR part 982), hereinafter referred to

as the “Order,” and the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act,” it is hereby directed that a referendum be conducted to ascertain whether continuance of the Order is favored by hazelnut growers. The referendum shall be conducted from October 28 to November 18, 2024, among hazelnut growers in the production area. Only current hazelnut growers that were also engaged in the production of hazelnuts during the period of July 1, 2023, through June 30, 2024, may participate in the continuance referendum.

USDA has determined that continuance referenda are an effective means for determining whether growers favor continuation of marketing order programs. USDA would consider termination of the Order if less than two-thirds of growers voting in the referendum, or growers of less than two-thirds of the volume represented in the referendum, favor continuance. In evaluating the merits of continuance versus termination, USDA will not exclusively consider the results of the continuance referendum. USDA will also consider all other relevant information concerning the operation of the Order and the relative benefits and costs to growers, handlers, and consumers to determine whether continued operation of the Order would tend to effectuate the declared policy of the Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the ballot materials used in the referendum have been approved by the Office of Management and Budget (OMB) and have been assigned OMB No. 0581–0178, Vegetable and Specialty Crops. It has been estimated that it will take an average of 20 minutes for each of the approximately 1,100 Oregon and Washington hazelnut growers to cast a ballot. Participation is voluntary. Ballots postmarked after November 18, 2024, will not be included in the vote tabulation.

Virginia Tjemsland and Barry Broadbent of the Northwest Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA, are hereby designated as the referendum agents of the Secretary of Agriculture to conduct this referendum. The procedure applicable to the referendum shall be

the “Procedure for the Conduct of Referenda in Connection with Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended” (7 CFR 900.400 through 900.407).

Ballots will be mailed to all hazelnut growers of record and may also be obtained from the referendum agents or their appointees.

List of Subjects in 7 CFR Part 982

Marketing agreements, Nuts, Reporting and recordkeeping requirements.

(Authority: 7 U.S.C. 601–674)

Erin Morris,
Associate Administrator, Agricultural Marketing Service.
[FR Doc. 2024–23446 Filed 10–9–24; 8:45 am]
BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2330; Project Identifier MCAI–2024–00393–T]

RIN 2120–AA64

Airworthiness Directives; ATR—GIE Avions de Transport Régional 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 ATR—GIE Avions de Transport Régional Model ATR42 and ATR72 airplanes. This proposed AD was prompted by a report of a manufacturing defect identified in the lavatory fire extinguisher. This defect could potentially result in leakage at the eutectic tip, leading to a loss of pressure in the cylinder, making fire extinguishing capabilities ineffective. This proposed AD would require an inspection (*i.e.*, weight check) and replacement, as applicable, of certain lavatory compartment fire extinguishers, and would also prohibit the installation of affected parts, as specified in a European Union Aviation Safety Agency

(EASA) AD, which is proposed for incorporation by reference (IBR). 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 November 25, 2024.

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 *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.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2330; 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.

Material Incorporated by Reference:

- For EASA material identified in this proposed AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADS@easa.europa.eu*; website *easa.europa.eu*. You may find this material on the EASA website at *ad.easa.europa.eu*. It is also available at *regulations.gov* under Docket No. FAA–2024–2330.

- 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.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; 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 the **ADDRESSES** section. Include “Docket No. FAA–2024–2330; Project Identifier MCAI–2024–00393–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 *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, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; 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 2024–0132, dated July 9, 2024 (EASA AD 2024–0132) (also referred to as the MCAI), to correct an unsafe condition for all Model ATR42–200, ATR42–300, ATR42–320, ATR42–400, and ATR42–500 airplanes; and Model ATR72–101, ATR72–102, ATR72–201, ATR72–202, ATR72–211, ATR72–212, and ATR72–212A airplanes.

Model ATR42–400 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore

does not include those airplanes in the applicability. The MCAI states a manufacturing defect was identified in the lavatory fire extinguisher. This defect could potentially result in leakage at the eutectic tip, leading to a loss of pressure in the cylinder, making fire extinguishing capabilities ineffective. This condition, if not detected and corrected, in combination with fire in the lavatory waste bin, could result in the propagation of an uncontrolled fire.

The FAA is proposing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2330.

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2024–0132 specifies procedures for the inspection (*i.e.*, weight check) and replacement, if any discrepancy is found (*i.e.*, the measured weight is more than 2.0 grams below the gross weight stated on the product label), of certain lavatory compartment fire extinguishers and 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 this 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 2024–0132 described previously, 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 2024–0132 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0132 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 2024–0132 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 2024–0132. Material required by EASA AD 2024–

0132 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–2330 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 77 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTION

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hours × \$85 per hour = \$85	\$0	\$85	\$6,545

The FAA estimates the following costs to do any necessary on-condition action 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 this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTION

Labor cost	Parts cost	Cost per product
1 work-hour × \$85 per hour = \$85	\$640	\$725

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:

ATR—GIE Avions de Transport Régional:
Docket No. FAA–2024–2330; Project Identifier MCAI–2024–00393–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 25, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all ATR—GIE Avions de Transport Régional Model ATR42–200, ATR42–300, ATR42–320, and ATR42–500 airplanes; and Model ATR72–101, ATR72–102, ATR72–201, ATR72–202, ATR72–211, ATR72–212, and ATR72–212A airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2024–0132, dated July 9, 2024 (EASA AD 2024–0132).

(d) Subject

Air Transport Association (ATA) of America Code 26, Fire protection.

(e) Unsafe Condition

This AD was prompted by a report of a manufacturing defect identified in the lavatory fire extinguisher. This defect could potentially result in leakage at the eutectic tip, leading to a loss of pressure in the cylinder, making fire extinguishing capabilities ineffective. The FAA is issuing this AD to address this condition, which if not detected and corrected, in combination with fire in the lavatory waste bin, could result in the propagation of an uncontrolled fire.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0132.

(h) Exceptions to EASA AD 2024–0132

(1) Where EASA AD 2024–0132 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2024–0132 defines a serviceable part as “Any lavatory (waste bin) compartment fire extinguishers, eligible for installation in accordance with ATR instructions, which is not an affected part,” for this AD replace that text with “Any lavatory (waste bin) compartment fire extinguishers, eligible for installation, which is not an affected part.”

(3) This AD does not adopt the “Remarks” section of EASA AD 2024–0132.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. 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 International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: 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, International Validation Branch, FAA; or EASA; or ATR—GIE Avions de Transport Régional’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Additional Information

For more information about this AD, contact Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3220; email shahram.daneshmandi@faa.gov.

(k) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2024–0132, dated July 9, 2024.

(ii) Reserved

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; website easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.

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

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locationsoremailfr.inspection@nara.gov.

Issued on October 4, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–23432 Filed 10–9–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF DEFENSE**Defense Acquisition Regulations System****48 CFR Parts 234, 242, and 252**

[Docket DARS–2024–0031]

RIN 0750–AL47

Defense Federal Acquisition Regulation Supplement: Cost and Software Data Reporting for Major Weapons Systems (2021–D028)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement statutory and other policy updates made to the cost and software data reporting requirements for major systems.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before December 9, 2024, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2021–D028, using either of the following methods:

○ *Federal eRulemaking Portal:* <https://www.regulations.gov>. Search for DFARS Case 2021–D028. Select “Comment” and follow the instructions to submit a comment. Please include “DFARS Case 2021–D028” on any attached documents.

○ *Email:* osd.dfars@mail.mil. Include DFARS Case 2021–D028 in the subject line of the message.

Comments received generally will be posted without change to <https://www.regulations.gov>, including any personal information provided. To confirm receipt of your comment(s), please check <https://www.regulations.gov>, approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Mr. Jon M. Snyder, telephone 703–945–5341.

SUPPLEMENTARY INFORMATION:**I. Background**

DoD is proposing to revise the DFARS to implement 10 U.S.C. 3227(b) and (c) and updates to the DFARS cost and software data reporting requirements made in the Department of Defense Instruction (DoDI) 5000.73, Cost Analysis Guidance and Procedures, and Department of Defense Manual (DoDM) 5000.04, Cost and Software Data Reporting (CSDR). Paragraphs (b) and (c) of 10 U.S.C. 3227 require, unless waived, submission of cost data for contracts expected to exceed \$20 million or \$50 million for acquisition and sustainment programs expected to exceed \$100 million. The data will facilitate cost estimation and comparison across acquisition programs. The changes to the DoDI and the DoDM implement DoDI 5000.02, Operation of the Adaptive Acquisition Framework, which restructured defense acquisition guidance to improve process effectiveness and implement the Adaptive Acquisition Framework.

II. Discussion and Analysis

This rule proposes to modify DFARS subpart 234.71 to implement 10 U.S.C. 3227(b) and (c) and the updates made to DoDI 5000.73 and DoDM 5000.04 resulting from implementation of the Adaptive Acquisition Framework. This proposed rule amends DFARS subpart 234.71 to establish policy and procedures necessary to implement the updates to DoDI 5000.73 and DoDM 5000.04.

The rule also proposes to modify the DFARS to revise cost and software data reporting requirements for contracts above certain thresholds when awarded in support of acquisition or sustainment programs expected to exceed \$100 million. This proposed rule modifies DFARS 242.503 to remove cost and software data reporting from postaward conference procedures, because the cost and software data reporting is a separate process.

The solicitation provision at 252.234–7003, Notice of Cost and Software Data Reporting, is proposed for deletion. Revisions are proposed to the contract clause at 252.234–7004, Cost and Software Data Reporting.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This rule proposes to delete the solicitation provision and its Alternate I at DFARS 252.234–7003, Notice of Cost and Software Data Reporting, and proposes to rename and amend the clause and its Alternate I at DFARS 252.234–7004, Cost and Software Data Reporting. The basic clause at DFARS 252.234–7004 is prescribed at 234.7105(a) and the alternate I clause is prescribed at 234.7105(b). However, this proposed rule does not impose any new requirements on contracts at or below the SAT, for commercial products including COTS items, or for commercial services. The clause does not apply to acquisitions at or below the SAT, to acquisitions of commercial products (including COTS items), or to acquisitions of commercial services.

IV. Expected Impact of the Rule

The proposed rule, if finalized, will impact the Government and large and small contractors. Contracting officers will be required to address CSDR requirements in acquisition plans and are now strongly encouraged to attend CSDR-readiness reviews for contracts meeting the updated thresholds.

Currently, contractors are required to comply with CSDR requirements for major defense acquisition programs. This proposed rule, if finalized, will require approximately 304 unique contractors (including about 112 small entities) per year to comply with CSDR reporting requirements for approximately 6,208 contracts (including about 358 awarded to small entities) per year expected to exceed \$20 million and \$50 million in support of acquisition and/or sustainment programs expected to exceed \$100 million under certain acquisition pathways. Contractors will also be required to comply with CSDR requirements for any contract for a program that is expected to exceed \$100 million, which the CSDR plan approval authority determines is high risk or of high technical interest.

DoD expects to benefit by having access to cost and software data for acquisition and sustainment programs in the various acquisition pathways.

This data will allow DoD to accomplish more accurate cost estimation and comparison across acquisition programs.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Regulatory Flexibility Act

DoD does not expect this proposed rule, when finalized, to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because this proposed rule only applies to contracts expected to exceed \$20 million or \$50 million for acquisition and sustainment programs expected to exceed \$100 million. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This proposed rule is required to implement 10 U.S.C. 3227(b) and (c) and updates made to DoDI 5000.73, Cost Analysis Guidance and Procedures, and DoDM 5000.04, Cost and Software Data Reporting. Unless waived, 10 U.S.C. 3227(b) and (c) require submission of cost data for contracts expected to exceed \$20 million or \$50 million for acquisition and sustainment programs expected to exceed \$100 million. The data will facilitate cost estimation and comparison across acquisition programs. The updates to the DoDI and DoDM implement DoDI 5000.02, Operation of the Adaptive Acquisition Framework, which restructured defense acquisition guidance to improve process effectiveness and implement the Adaptive Acquisition Framework.

The objective of this proposed rule is to update the DFARS cost and software data reporting requirements to implement 10 U.S.C. 3227(b) and (c) and changes made to DoDI 5000.73, Cost Analysis Guidance and Procedures, and DoDM 5000.04, Cost and Software Data Reporting. The legal basis for this

proposed rule is 41 U.S.C. 1303 and 10 U.S.C. 3227(b) and (c).

This proposed rule, when finalized, will require the clause at DFARS 252.234–7004, Cost and Software Data Reporting System, to be included in solicitations and contracts that are expected to exceed \$50 million and that meet the requirements for cost and software data reporting. The proposed rule, when finalized, will require alternate I of the clause to be included in solicitations and contracts that are expected to be greater than \$20 million, but less than or equal to \$50 million, when required by the Cost and Software Data Reporting plan approval authority or when determined to be high-risk or of high-technical interest by the cost and software data reporting plan approval authority. Therefore, DoD considered contracts with this clause that were awarded during the last three fiscal years. According to data from the Procurement Business Intelligence Service, in the last three fiscal years, DoD awarded such contracts to unique small entities as follows: 130 in FY 2021, 99 in FY 2022, and 109 in FY 2023, which averages out to 112 per fiscal year. Therefore, the number of small entities to which this proposed rule may apply is approximately 112.

This proposed rule does not impose any new reporting, recordkeeping, or other compliance requirements for small entities.

This proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known alternatives that would accomplish the stated objectives of the applicable statute.

DoD invites comments from small business concerns and other interested parties on the expected impact of this proposed rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this proposed rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2021–D028), in correspondence.

VII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies to this proposed rule. However, these changes to the DFARS do not impose additional information collection requirements to the paperwork burden previously approved by the Office of Management and Budget (OMB) under OMB Control Number 0704–0671, entitled Cost and Software Data Reporting, and OMB Control Number 9000–0149, entitled

Subcontract Consent and Contractors' Purchasing System Review.

List of Subjects in 48 CFR Parts 234, 242, and 252

Government procurement.

Jennifer D. Johnson,
Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System proposes to amend 48 CFR parts 234, 242, and 252 as follows:

■ 1. The authority citation for 48 CFR parts 234, 242, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 234—MAJOR SYSTEM ACQUISITION

■ 2. Revise section 234.7100 to read as follows:

234.7100 Scope of subpart.

This subpart implements 10 U.S.C. 3227(b) and (c).

■ 3. Revise section 234.7101 to read as follows:

234.7101 Applicability.

(a) This subpart applies to contracts supporting any acquisition and/or sustainment program, if that program is expected to exceed \$100 million in one or more of the following acquisition pathways and to meet the following program criteria, when the contract is expected to exceed either of the following amounts:

(1) \$50 million.

TABLE 1 TO PARAGRAPH (a)(1)

Acquisition pathway	Program criteria
Major Capability Acquisition	Acquisition Category (ACAT) I–II.
Software Pathway	Programs expected to exceed \$100 million in acquisition expenditures over any 5-year period.
Defense Business Systems	Business Category (BCAT) I–II expected to exceed \$100 million in acquisition expenditures over any 5-year period.
Services	Services Category (SCAT) I.
Middle Tier Acquisition	Programs expected to exceed \$100 million in acquisition expenditures over the Middle Tier Acquisition period.

(2) \$20 million.

TABLE 2 TO PARAGRAPH (a)(2)

Acquisition pathway	Program criteria
Major Capability Acquisition	If required by the Cost and Software Data Reporting plan approval authority.
Software Pathway.	
Defense Business Systems.	
Services.	
Middle Tier Acquisition.	
Urgent Capability Acquisition.	
Other Acquisition Programs.	

(b) This subpart also applies to contracts supporting any other program that is expected to exceed \$100 million and is determined to be high-risk or of high-technical interest by the cost and software reporting (CSDR) plan approval authority.

■ 4. Add sections 234.7102 through 234.7105 to read as follows:

* * * * *

Sec.

234.7102 Policy.

234.7103 Waiver.

234.7104 Procedures.

234.7105 Contract clause.

* * * * *

234.7102 Policy.

The CSDR requirements are specified in DoD Instruction (DoDI) 5000.73, Cost Analysis Guidance and Procedures, and are mandatory for acquisitions as specified in DoDI 5000.02, Operation of the Adaptive Acquisition Framework. Additional requirements for CSDR reporting are specified in DoD Manual

(DoDM) 5000.04, Cost and Software Data Reporting.

234.7103 Waiver.

(a) The CSDR requirements identified in this subpart may be waived only by the Office of the Secretary of Defense, Director of Cost Assessment and Program Evaluation (see 10 U.S.C. 3227(c)).

(b) See PGI 234.7103 for contact information for the Cost Assessment and Program Evaluation office.

234.7104 Procedures.

(a) If an indefinite-delivery contract is awarded, the contracting officer shall ensure the applicability of CSDR requirements is specified at the task order or delivery order level.

(b) Prior to the issuance of a solicitation, the contracting officer shall obtain from the program manager, or other official responsible for the program, written documentation that preaward requirements of DoDM

5000.04 have been met or include a signed CSDR waiver in the contract file.

(c) The contracting officer should attend the CSDR-readiness review for contracts that include the basic or alternate of the clause at 252.234–7004, Cost and Software Data Reporting (see DoDM 5000.04).

234.7105 Contract clause.

Use the basic or the alternate of the clause at 252.234–7004, Cost and Software Data Reporting, in solicitations and contracts for defense acquisition programs that are expected to exceed \$100 million and meet the requirements for cost and software data reporting as follows:

(a) Use the basic clause in solicitations and contracts that exceed \$50 million and meet the criteria at 234.7101(a) and (a)(1).

(b) Use the alternate clause in solicitations and contracts that exceed \$20 million, but are less than or equal to \$50 million, and that meet the criteria at 234.7101(a)(2) or (b).

PART 242—CONTRACT ADMINISTRATION AND AUDIT SERVICES

■ 5. Revise section 242.503–2 to read as follows:

242.503–2 Postaward conference procedure.

DD Form 1484, Post-Award Conference Record, may be used in conducting the conference and in preparing the conference report.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.234–7003 [Removed and Reserved]

■ 6. Remove and reserve section 252.234–7003.

■ 7. Revise section 252.234–7004 to read as follows:

252.234–7004 Cost and Software Data Reporting.

As prescribed in 234.7105(a), use the following basic clause:

Cost and Software Data Reporting—Basic (DATE)

(a) *Definition.* As used in this clause—
Unfinalized contract action means any contract action for which the contract terms, specifications, or price are not agreed upon before performance is begun under the action. Examples are letter contracts, orders under basic ordering agreements, and provisioned item orders, for which the price has not been agreed upon before performance has begun.

(b) *Requirements.* In the performance of this contract, the Contractor shall—

(1) Use cost and software data reporting (CSDR) processes and procedures that accomplish the requirements contained in the contract CSDR Plan (DD Form 2794) and applicable data item description(s);

(2) Establish, implement, and maintain processes and procedures that provide for the consistent collection and generation of reliable actual cost data required by the contract CSDR Plan (DD Form 2794) and applicable data item description(s); and

(3)(i) Within 60 days of contract award or the finalization of an unfinalized contract action, complete a CSDR-readiness review with the Cost Assessment and Program Evaluation, Deputy Director for Cost Assessment and the cost estimating component of the relevant military department or defense agency in order to review CSDR requirements.

(ii) During the CSDR-readiness review, the Contractor shall—

(A) Describe the processes and procedures the Contractor will use to—

(1) Provide for the consistent collection and generation of reliable CSDR data; and

(2) Deliver timely CSDR data deliverables required by the contract CSDR Plan (DD Form 2794) and applicable data item description(s);

(B) Identify any subcontractor whose contract is expected to exceed \$50 million; and

(C) Identify any potential revisions to CSDR requirements that may better align data reporting to the Contractor's procedures.

(c) *Notification.* For subcontracts expected to exceed \$50 million, if the Contractor changes subcontractors or awards new subcontracts, the Contractor shall notify the Contracting Officer within 10 days of award.

(d) *Subcontracts.* The Contractor shall include this clause in subcontracts at any tier that are expected to exceed \$50 million.

(End of clause)

Alternate I. As prescribed in 234.7105(b), use the following clause, which uses different paragraphs (b)(3)(ii)(B), (c), and (d) than the basic clause:

Cost and Software Data Reporting—Alternate I (DATE)

(a) *Definition.* As used in this clause—
Unfinalized contract action means any contract action for which the contract terms, specifications, or price are not agreed upon before performance is begun under the action. Examples are letter contracts, orders under basic ordering agreements, and provisioned item orders, for which the price has not been agreed upon before performance has begun.

(b) *Requirements.* In the performance of this contract, the Contractor shall—

(1) Use cost and software data reporting (CSDR) processes and procedures that accomplish the requirements contained in the contract CSDR Plan (DD Form 2794) and applicable data item description(s);

(2) Establish, implement, and maintain processes and procedures that provide for the consistent collection and generation of reliable actual cost data required by the contract CSDR Plan (DD Form 2794) and applicable data item description(s); and

(3)(i) Within 60 days of contract award or the finalization of an unfinalized contract action, complete a CSDR-readiness review with the Cost Assessment and Program Evaluation, Deputy Director for Cost Assessment and the cost estimating component of the relevant military department or defense agency in order to review CSDR requirements.

(ii) During the CSDR-readiness review, the Contractor shall—

(A) Describe the processes and procedures the Contractor will use to—

(1) Provide for the consistent collection and generation of reliable CSDR data; and

(2) Deliver timely CSDR data deliverables required by the contract CSDR Plan (DD Form 2794) and applicable data item description(s);

(B) Identify any subcontractor whose contract is expected to exceed \$20 million; and

(C) Identify any potential revisions to CSDR requirements that may better align data reporting to the Contractor's procedures.

(c) *Notification.* For subcontracts expected to exceed \$20 million, if the Contractor changes subcontractors or awards new

subcontracts, the Contractor shall notify the Contracting Officer within 10 days of award.

(d) *Subcontracts.* The Contractor shall include this clause in subcontracts at any tier that are expected to exceed \$20 million.

(End of clause)

[FR Doc. 2024–23229 Filed 10–9–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 252

[Docket DARS–2024–0032]

RIN 0750–AM22

Defense Federal Acquisition Regulation Supplement: 8(a) Program (DFARS Case 2024–D025)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to revise joint venture eligibility requirements and nonmanufacturer rule applicability to 8(a) contracts awarded pursuant to the 8(a) Partnership Agreement between DoD and the Small Business Administration. These changes are necessary to align the DFARS with the Federal Acquisition Regulation (FAR).

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before December 9, 2024, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2024–D025, using either of the following methods:

○ *Federal eRulemaking Portal:* <https://www.regulations.gov>. Search for DFARS Case 2024–D025. Select “Comment” and follow the instructions to submit a comment. Please include “DFARS Case 2024–D025” on any attached documents.

○ *Email:* osd.dfars@mail.mil. Include DFARS Case 2024–D025 in the subject line of the message.

Comments received generally will be posted without change to <https://www.regulations.gov>, including any personal information provided. To confirm receipt of your comment(s), please check <https://www.regulations.gov>, approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT:
Jeanette Snyder, telephone 703–508–7524.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to align with changes made to the FAR via the final rules published in the **Federal Register** on August 11, 2021 (86 FR 44233) and on September 23, 2022 (87 FR 58219). The final rule for FAR Case 2016–011, Revision of Limitations on Subcontracting, published on August 11, 2021, standardized the application of the nonmanufacturer rule requirements for the socioeconomic programs identified at FAR 19.000(a)(3). The final rule for FAR Case 2017–019, Policy on Joint Ventures, published on September 23, 2022, clarified the eligibility of joint ventures under the 8(a) Program.

This rule is also proposing to revise the DFARS to align with the proposed rule for FAR Case 2021–020, Limitations on Subcontracting Revisions, published on January 17, 2024 (89 FR 2910). This FAR rule proposed to remove the nonmanufacturer rule requirements for 8(a) participants from FAR 19.809–2 as was intended to be accomplished via the final rule published on August 11, 2021, and to remove the kit assembler rule set from the nonmanufacturer rule. This DFARS rule proposes to make similar changes.

II. Discussion and Analysis

This rule proposes to modify the contract clause at DFARS 225.219–7010, Notification of Competition Limited to Eligible 8(a) Participants—Partnership Agreement, to add joint ventures to the list of concerns from whom offers are solicited for 8(a) Program acquisitions that are processed in accordance with the 8(a) Partnership Agreement between DoD and the Small Business Administration (SBA) (the Agreement). This proposed rule also includes the removal of the kit assembler rule set and the nonmanufacturer rule requirements addressed in paragraphs (d)(1), (d)(2), and (d)(3) of the clause at DFARS 252.219–7010 to align with the clause at FAR 52.219–33, Nonmanufacturer Rule, which specifies the nonmanufacturer rule requirements for all socioeconomic categories.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This proposed rule amends the clause at DFARS 225.219–7010, Notification of

Competition Limited to Eligible 8(a) Participants—Partnership Agreement; however, this proposed rule does not impose any new requirements on contracts at or below the SAT, for commercial products including COTS items, or for commercial services. The clause will continue to not apply to acquisitions at or below the SAT and will continue to apply to acquisitions of commercial products including COTS items, and to acquisitions of commercial services.

IV. Expected Impact of the Rule

This proposed rule, when finalized, is expected to impact 8(a) participants, including 8(a) joint ventures, who enter into contracts with DoD that are processed in accordance with the Agreement. These participants will be required to comply with the nonmanufacturer rule requirements in the clause at FAR 52.219–33. As a result, DoD may see an increase in the number of 8(a) participants that submit proposals for contracts processed in accordance with the Agreement, which may expand the defense industrial base.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Regulatory Flexibility Act

DoD does not expect this proposed rule, when finalized, to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because this rule merely updates the DFARS to align with the FAR. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This proposed rule is necessary to revise the contract clause at DFARS 252.219–7010, Notification of Competition Limited to Eligible 8(a) Participants—Partnership Agreement, to align with changes made to the FAR regarding joint venture eligibility for

8(a) Program acquisitions processed in accordance with the 8(a) Partnership Agreement between DoD and the Small Business Administration (SBA). This proposed rule also removes the nonmanufacturer rule requirements from the clause to align with changes made to the FAR.

The objective of the rule is to revise the DFARS to align with amendments made to the FAR. The legal basis for the rule is 41 U.S.C. 1303.

According to data from the Procurement Business Intelligence Service, in the last three fiscal years DoD awarded contracts that included the clause at DFARS 252.219–7010 to unique small entities as follows: 848 in fiscal year 2021; 553 in fiscal year 2022; 600 in fiscal year 2023. This averages out to 667 per fiscal year. Therefore, DoD estimates that the number of small entities to which this rule will apply is approximately 667.

This proposed rule does not impose any new reporting, recordkeeping, or other compliance requirements for small entities.

This proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

DoD did not identify any significant alternatives to the proposed rule. Any impact is expected to be beneficial.

DoD invites comments from small business concerns and other interested parties on the expected impact of this proposed rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this proposed rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2024–D025), in correspondence.

VII. Paperwork Reduction Act

This proposed rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 252

Government procurement.

Jennifer D. Johnson,
Editor/Publisher, Defense Acquisition Regulations System.

Therefore, the Defense Acquisition Regulations System proposes to amend 48 CFR part 252 as follows:

**PART 252—SOLICITATION
PROVISIONS AND CONTRACT
CLAUSES**

■ 1. The authority citation for 48 CFR part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Revise and republish section 252.219–7010 to read as follows:

252.219–7010 Notification of Competition Limited to Eligible 8(a) Participants—Partnership Agreement.

As prescribed in 219.811–3(2), use the following clause:

Notification of Competition Limited to Eligible 8(a) Participants—Partnership Agreement (DATE)

(a) Offers are solicited only from—
(1) Small business concerns expressly certified by the Small Business Administration (SBA) for participation in SBA's 8(a) Program and which meet the

following criteria at the time of submission of offer:

(i) The Offeror is in conformance with the 8(a) support limitation set forth in its approved business plan.

(ii) The Offeror is in conformance with the Business Activity Targets set forth in its approved business plan or any remedial action directed by SBA.

(iii) If the competition is to be limited to 8(a) concerns within one or more specific SBA regions or districts, then the Offeror's approved business plan is on file and serviced by _____. *[Contracting Officer completes by inserting the appropriate SBA District and/or Regional Office(s) as identified by SBA.]*

(2) A joint venture, in which at least one of the 8(a) program participants that is a party to the joint venture complies with the criteria set forth in paragraph (a)(1) of this clause, and that has a joint venture agreement that complies with 13 CFR 124.513(c); or

(3) A joint venture—

(i) That is comprised of a mentor and an 8(a) protégé with an approved mentor-protégé agreement under an SBA mentor-protégé program;

(ii) In which at least one of the 8(a) program participants that is a party to the joint venture complies with the criteria set forth in paragraph (a)(1) of this clause; and

(iii) With a joint venture agreement that complies with 13 CFR 124.513(c).

(b) By submission of its offer, the Offeror represents that it meets the applicable criteria set forth in paragraph (a) of this clause.

(c) Any award resulting from this solicitation will be made directly by the Contracting Officer to the successful 8(a) offeror selected through the evaluation criteria set forth in this solicitation.

(d) The _____ *[insert name of SBA's contractor]* will notify the _____ *[insert name of contracting agency]* Contracting Officer in writing immediately upon entering an agreement (either oral or written) to transfer all or part of its stock or other ownership interest to any other party.

(End of clause)

[FR Doc. 2024–23230 Filed 10–9–24; 8:45 am]

BILLING CODE 6001–FR–P

Notices

Federal Register
Vol. 89, No. 197
Thursday, October 10, 2024

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FGIS–24–0028]

Certification of Export Port Locations for Alabama and Washington and Geographic Areas Under the Delegated Authority of United States Grain Standards Act

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) is announcing the certification of the Alabama Department of Agriculture and Industries and the Washington State Department of

Agriculture to provide official inspection services at the export port locations listed in table 1, below, under the delegated authority of the United States Grain Standards Act (USGSA or Act), as amended. AMS is also announcing the designation of official agencies to provide official services (at other than export port locations) in the geographic areas listed in table 2, below.

FOR FURTHER INFORMATION CONTACT: Jennifer Weiland, Grain Marketing Specialist, Telephone 202–989–5995; Email: Jennifer.j.weiland@usda.gov or FGISQACD@usda.gov.

SUPPLEMENTARY INFORMATION:

I. Certification of Delegated State Agencies

This notice announces AMS’s certification that the Alabama Department of Agriculture and Industries and the Washington State Department of Agriculture are meeting the criteria required to perform official services at export port locations in the States of Alabama and Washington, respectively. Section 7(e) of the USGSA (7 U.S.C. 79(e)) requires the Secretary of Agriculture (Secretary) to certify, every

five years, that each State agency with a delegation of authority is meeting the criteria described in section 7(f)(1)(A) of the Act for carrying out inspections on behalf of the Secretary. Under the certification process prescribed by the statute, the Secretary must: (1) publish in the **Federal Register** a notice of intent to certify a State agency and provide a 30-day period for public comment; (2) evaluate the public comments received and, in accordance with section 7(e)(3) of the Act, conduct an investigation to determine whether the State agency is qualified; (3) make findings based on the public comments received and the investigation conducted; and (4) publish a notice in the **Federal Register** announcing whether the certification has been granted and describing the basis on which the Secretary made the decision.

For more information about the delegation and certification processes, please see 7 CFR 800.195. Table 1 provides relevant information about the delegations of authority to the Alabama and Washington State agencies to perform official services at export port locations.

TABLE 1—DELEGATED STATE AGENCIES PROVIDING SERVICES AT EXPORT PORT LOCATIONS

State agency	Geographic area	Delegation		
		Area descriptions	Starts	Ends
Alabama Department of Agriculture and Industries, Montgomery, AL 251–331–1597. Washington Department of Agriculture, Olympia, WA 360–902–1921.	Montgomery, AL	88 FR 14593 (3/9/2023)	1/1/2023	12/31/2027
	Olympia, WA	88 FR 14593 (3/9/2023)	1/1/2023	12/31/2027

A. Alabama Department of Agriculture and Industries

AMS published a notice of intent to certify the Alabama Department of Agriculture and Industries and requested comments on the quality of services the State agency provided at export port locations in Alabama in the March 9, 2023 edition of the **Federal Register** (88 FR 14593). Comments were due 30 days after the date of publication. AMS did not receive any negative comments regarding the State agency’s performance. AMS also considered internal feedback on agency performance in areas such as grading accuracy, equipment testing, equipment monitoring, and adherence to testing

protocols required for mycotoxins and falling number values, among others. In addition, AMS conducted a compliance review of the State agency that evaluated its ability to provide timely, accurate, and non-discriminatory services, including timely and accurate issuance of certificates; implement a quality assurance program; conduct routine testing of equipment and scales; designate a qualified manager to oversee the execution of these required duties; and meet other requirements as specified in section 7(f)(1)(A) of the USGSA.

AMS also conducted an investigation to determine whether the Alabama State agency is qualified to perform inspections under section 7(e)(3) of the

USGSA (7 U.S.C. 79(e)(3)). Pursuant to this section, AMS consulted with USDA’s Office of Inspector General (OIG), the Department of Justice (DOJ), and the Government Accountability Office (GAO).¹ Neither the compliance review nor the consultations produced findings that would negatively impact the Alabama State agency’s ability to perform official inspections at export port locations. Accordingly, AMS certifies that the Alabama Department of Agriculture and Industries is meeting the criteria required to perform official

¹ GAO advised that it does not have authority over State agencies and was unable to provide relevant information.

services at export port locations in Alabama.

B. Washington State Department of Agriculture

AMS published a notice of intent to certify the Washington State Department of Agriculture and requested comments on the quality of services the State agency provided at export port locations in Washington in the March 9, 2023 edition of the **Federal Register** (88 FR 14593). Comments were due 30 days after the date of publication. AMS did not receive any negative comments regarding the State agency's performance. AMS also considered internal feedback on agency performance in areas such as grading accuracy, equipment testing, equipment monitoring, and adherence to testing protocols required for mycotoxins and falling number values, among others. Additionally, AMS conducted a compliance review of the State agency that evaluated its ability to provide timely, accurate, and non-discriminatory services, including

timely and accurate issuance of certificates; implement a quality assurance program; conduct routine testing of equipment and scales; designate a qualified manager to oversee the execution of these required duties; and meet other requirements as specified in section 7(f)(1)(A) the USGSA.

AMS also conducted an investigation to determine whether the Washington State agency is qualified to perform inspections under section 7(e)(3) of the USGSA (7 U.S.C. 79(e)(3)). Pursuant to this section, AMS consulted with USDA's OIG, DOJ, and GAO. Neither the compliance review nor the consultations produced findings that would negatively impact the Washington State agency's ability to perform official inspections at export port locations. Accordingly, AMS certifies that the Washington State Department of Agriculture is meeting the criteria required to provide official services at export port locations in Washington.

II. Designation of Official Agencies

This notice announces AMS's designation and/or renewal of the designation of the official agencies listed in table 2, below, to provide official services at locations other than export port locations. Section 7(f) of the USGSA (7 U.S.C. 79(f)) authorizes the Secretary to designate a qualified applicant to provide official services in a specified area after determining that the applicant is better able than any other applicant to provide such official services. A designated agency may provide official inspection services and/or Class X or Class Y weighing services at locations other than export port locations. Under section 7(g) of the USGSA, designations of official agencies are effective for no longer than five years but may be renewed according to the criteria and procedures prescribed in section 7(f) of the Act. For more information about the designation and renewal processes, please see 7 CFR 800.196. To view the applications for these areas, please contact FGISQACD@usda.gov.

TABLE 2—DESIGNATED OFFICIAL AGENCIES PROVIDING SERVICES AT OTHER THAN EXPORT PORTS

Official Agency	Geographic area	Delegation		
		Area descriptions	Starts	Ends
North Dakota Grain Inspection Services, Inc., Decatur, IN 701–293–7420 (NDGI) ² .	Decatur, IN	See sec. II.B., below	1/1/2021	12/31/2025
Plainview Grain Inspection and Weighing Service, Inc. Plainview, TX 806–293–1364 (Plainview) ³ .	Plainview, TX	See sec II.A., below	4/1/2022	3/31/2027
Montana Department of Agriculture Helena, MT 406–452–95671 (Montana).	Helena, MT	86 FR 58247 (10/21/2021)	7/1/2022	6/30/2027
Aberdeen Grain Inspection, Inc. Aberdeen, SD 605–225–8432 (Aberdeen).	Aberdeen, SD	87 FR 51053 (8/19/2022) ..	10/1/2022	9/30/2027
Hastings Grain Inspection, Inc. Hastings, NE 402–462–4254 (Hastings).	Hastings, NE	87 FR 51053 (8/19/2022) ..	10/1/2022	9/30/2027
Missouri Department of Agriculture Jefferson City, MO 573–751–5515 (Missouri).	Jefferson City, MO	87 FR 51053 (8/19/2022) ..	10/1/2022	9/30/2027
Alabama Department of Agriculture and Industries Montgomery, AL 251–331–1597 (Alabama).	Montgomery, AL	87 FR 51053 (8/19/2022) ..	1/1/2023	12/31/2027
Washington Department of Agriculture Olympia, WA 360–902–1921 (Washington).	Olympia, WA	87 FR 51053 (8/19/2022) ..	1/1/2023	12/31/2027
Kankakee Grain Inspection, Inc. Essex, IL 815–365–2268 (Kankakee).	Essex, IL	87 FR 51053 (8/19/2022) ..	1/1/2023	12/31/2027
Jamestown Grain Inspection, Inc., Jamestown, ND 701–252–1290 (Jamestown).	Jamestown, ND	88 FR 19051 (3/30/2023) ..	4/1/2023	3/31/2028
Lincoln Inspection Service, Inc. Lincoln, NE 402–435–4386 (Lincoln).	Lincoln, NE	88 FR 19051 (3/30/2023) ..	4/1/2023	3/31/2028
Midsouth Grain Inspection Service Memphis, TN 901–942–3216 (Midsouth).	Memphis, TN	88 FR 19051 (3/30/2023) ..	4/1/2023	3/31/2028
Kansas Grain Inspection Service, Inc. Topeka, KS 785–233–7063 (Kansas Grain).	Topeka, KS	88 FR 19051 (3/30/2023) ..	7/1/2023	6/30/2028
Mid-Iowa Grain Inspection, Inc. Cedar Rapids, IA 319–533–4666 (Mid-Iowa).	Cedar Rapids, IA	88 FR 19051 (3/30/2023) ..	7/1/2023	6/30/2028
Minot Grain Inspection, Inc. Minot, ND 701–838–1734 (Minot).	Minot, ND	88 FR 19051 (3/30/2023) ..	7/1/2023	6/30/2028
Tri-State Grain Inspection Service Inc., Cincinnati, OH 513–225–5095 (Tri-State).	Cincinnati, OH	88 FR 19051 (3/30/2023) ..	7/1/2023	6/30/2028
Grain Inspection Services of Texas LLC, Saginaw, TX 817–542–7338 (GIST) ⁴ .	Saginaw, TX	See sec. II.A., below	7/1/2024	6/30/2027

AMS requested comments on the services provided by the official agencies listed in table 2.⁵ AMS also sought applications from interested private and State entities to provide official inspection and weighing services in the listed geographic areas.

The requests were published in the **Federal Register**, and each offered a 30-day comment period from the publication date. AMS did not receive any negative comments regarding the performance of the official agencies. Table 3, below, identifies the editions of

the **Federal Register** in which AMS provided notice of the designation opportunities for the listed geographic areas and requested comments on the listed official agencies.

TABLE 3—FEDERAL REGISTER NOTICES ANNOUNCING OPPORTUNITIES FOR GEOGRAPHIC AREAS AND REQUESTING COMMENTS

Official Agency	Geographic area	Federal Register
Montana	Helena, MT	86 FR 58247 (October 21, 2021).
Aberdeen, Hastings, Missouri, Alabama, Kankakee, Washington.	Aberdeen, SD; Hastings, NE; Jefferson City, MO; Montgomery, AL; Essex, IL; and Olympia, WA.	87 FR 51053 (August 19, 2022).
Jamestown, Lincoln, Midsouth, Kansas Grain, Mid-Iowa, Minot, Tri-State.	Jamestown, ND; Lincoln, NE; Memphis, TN; Topeka; KS, Cedar Rapids, IA; Minot, ND; and Cincinnati, OH.	88 FR 19051 (March 30, 2023).
Plainview, GIST	Texas Central Area	88 FR 19605 (April 3, 2023).
NDGI ⁶	Decatur, IN	88 FR 78283 (November 15, 2023).
		88 FR 78283 (November 15, 2023).

AMS also considered internal feedback on agency performance in areas such as grading accuracy, equipment testing, equipment monitoring, and adherence to testing protocols required for mycotoxins and falling number values, among others. In addition to requesting external and internal feedback, AMS conducted compliance reviews to assess the performance of the designated agencies. As part of these reviews, AMS evaluated the agencies' past compliance and supervision audit results; quality program performance; stability, quality, and consistency of service; cooperation with FGIS; adequacy of resources; timely service and issuance of certificates; and cost of inspection services. If instances of noncompliance were found, agencies were required to correct the issues before their performance review was finalized. All the listed agencies performed well during their compliance reviews and were determined to be compliant with USGSA requirements.

The official agencies listed in tables 2 and 3 for the designation areas of Decatur, Indiana; Helena, Montana; Aberdeen, South Dakota; Hastings, Nebraska; Jefferson City, Missouri; Montgomery, Alabama; Olympia, Washington; Essex, Illinois; Jamestown, North Dakota; Lincoln, Nebraska; Memphis, Tennessee; Topeka, Kansas; Cedar Rapids, Iowa; Minot, North

Dakota; and Cincinnati, Ohio were the only applicants for designation in those geographic areas. The only designation area for which more than one application was received is the Texas Central area, which is discussed in the next section.

A. Designation for the Texas Central Area

In the April 3, 2023, **Federal Register** (88 FR 19605), AMS requested comments about the need for USGSA inspection and weighing services in the Texas Central area as well applications for designation to provide official services in that area. AMS received designation applications from Plainview Grain Inspection and Weighing Service, Inc. (Plainview) and Grain Inspection Services of Texas (GIST). Plainview applied for designation for eight of the 149 counties and GIST applied for the entire 149-county area. Plainview is currently a designated official agency in good standing with AMS and the industry, and GIST is a new entity requesting designation.

In analyzing applications for the Texas Central geographic area, AMS evaluated applicants against the designation criteria in Section 7(f) of the USGSA (7 U.S.C. 79(f)), the recent audit report for Plainview detailing the applicant's performance of the designation criteria, customers' experience with the official service provider, public comments received

related to the designation opportunity notice, current service agreements, and details provided in the application. Applications generally include information on an applicant's business plan to service the area, active licenses and service availability, fees, overall service costs, and proximity to customers and facilities. Plainview meets the designation criteria established under the USGSA and is operating with comparable costs for most service requests. GIST is a new entity and first-time applicant that demonstrates the ability to meet the designation criteria. In consideration of these factors, AMS determined that awarding eight counties to Plainview and the remaining 141 counties to GIST is the best manner in which to continue servicing the area. As such, the description of Plainview's designation area is amended. The new areas allow for an expansion of Plainview's geographic area without overlapping boundaries or isolating customers or areas within another official service provider's geographic area. GIST will be awarded a newly defined geographic area.

The Texas Central counties awarded to Plainview and GIST are listed below and will be reflected in their respective designation Appendix A documents:

Plainview—Coke, Coleman, Ector, Glasscock, Midland, Runnels, Sterling, and Winkler. GIST—Anderson,

² The Decatur, Indiana area that was previously serviced by Northeast Indiana Grain Inspection, Inc. (NEIGI) is now serviced by North Dakota Grain Inspection Service, Inc. (NDGI), which was designated for other geographic areas in January 2021. Decatur, Indiana is a new geographic area for NDGI.

³ As of August 1, 2024, NDGI purchased the Detroit Grain Inspection Agency. NDGI requested transfer of that USGSA Geographic Area. FGIS approved the transfer and has updated the NDGI USGSA Designation documents in Appendix A.

⁴ The Central Texas area, which was previously an unassigned area, is now serviced by one current official agency, Plainview Grain Inspection and

Weighing Service, Inc. (Plainview) and one new official agency, Grain Inspection Services of Texas, LLC (GIST), in separate parts within.

⁵ AMS did not request comments on the services provided by NDGI in Decatur, Indiana because NDGI had not previously provided services in that designation area.

⁶ See footnote 5.

Angelina, Atascosa, Austin, Bandera, Bastrop, Bell, Bexar, Blanco, Bosque, Brazos, Brewster, Brown, Burleson, Burnet, Caldwell, Camp, Cherokee, Collin, Comal, Comanche, Concho, Cooke, Coryell, Crane, Crockett, Culberson, Dallas, Delta, Denton, DeWitt, Eastland, Edwards, Ellis, El Paso, Erath, Falls, Fannin, Fayette, Franklin, Freestone, Frio, Gillespie, Gonzales, Grayson, Gregg, Grimes, Guadalupe, Hamilton, Hardin, Harrison, Hays, Henderson, Hill, Hood, Hopkins, Houston, Hudspeth, Hunt, Irion, Jack, Jasper, Jeff Davis, Johnson, Karnes, Kaufman, Kendall, Kerr, Kimble, Kinney, Lamar, Lampasas, Lavaca, Lee, Leon, Liberty, Limestone, Llano, Loving, McCulloch, McLennan, Madison, Marion, Mason, Maverick, Medina, Menard, Milam, Mills, Montague, Montgomery, Morris, Nacogdoches, Navarro, Newton, Orange, Palo Pinto, Panola, Parker, Pecos, Polk, Presidio, Rans, Reagan, Real, Red River, Reeves, Robertson, Rockwall, Rusk, Sabine, San Augustine, San Jacinto, San Saba, Schleicher, Shelby, Smith, Somervell, Stephens, Sutton, Tarrant, Terrell, Titus, Tom Green, Travis, Trinity, Tyler, Upshur, Upton, Uvalde, Val Verde, Van Zandt, Walker, Ward, Washington, Williamson, Wilson, Wise, Wood, Young, and Zavala.

B. Designation for the Decatur, Indiana Area

In the November 15, 2023 edition of the **Federal Register** (88 FR 78283), AMS requested applications for designation to provide official services in the Decatur, Indiana geographic area previously serviced by Northeast Indiana Grain Inspection, Inc. AMS awarded the entire geographic area to NDGI, the sole applicant for the Decatur, IN geographic area. NDGI's Designation Appendix A documents have been updated to reflect the addition of the Decatur area described below.

In Indiana:

Bounded on the north by the northern LaGrange and Steuben County lines; bounded on the east by the eastern Steuben, De Kalb, Allen, and Adams County lines; bounded on the south by the southern Adams and Wells County lines; and bounded on the west by the western Wells County line; the southern Huntington and Wabash County lines; the western Wabash County line north to State Route 114; State Route 114 northwest to State Route 19; State Route 19 north to Kosciusko County; the western and northern Kosciusko County lines; the western Noble and LaGrange County lines.

Authority: 7 U.S.C. 71–87k.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2024–23448 Filed 10–9–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

U.S. Codex Office

Codex Alimentarius Commission: Meeting of the Codex Alimentarius Commission

AGENCY: U.S. Codex Office, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The U.S. Codex Office is sponsoring a public meeting on November 14, 2024. The objective of the public meeting is to provide information and receive public comments on agenda items and draft U.S. positions to be discussed at the 47th Session of the Codex Alimentarius Commission (CAC47), which will meet in Geneva, Switzerland from November 25, 2024 to November 30, 2024. The U.S. Manager for Codex Alimentarius and the Under Secretary for Trade and Foreign Agricultural Affairs recognize the importance of providing interested parties the opportunity to obtain background information on the 47th Session of the CAC and to address items on the agenda.

DATES: The public meeting is scheduled for November 14, 2024 from 1:00–4:00 p.m. ET.

ADDRESSES: The public meeting will take place via Video Teleconference only. Documents related to the 47th Session of the CAC will be accessible via the internet at the following address: <https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CAC&session=47>. The U.S. Delegate to the 47th Session of CAC invites interested U.S. parties to submit their comments electronically to the following email addresses: Ken.Lowery@usda.gov and uscodex@usda.gov.

Registration: Attendees may register to attend the public meeting here: <https://www.zoomgov.com/meeting/register/vJlscO2gqTksGsA8Tkj9C4wKEgJcqBY5PMI>. After registering, you will receive a confirmation email containing information about joining the meeting.

For further information about the 47th Session of the CAC, contact Kenneth Lowery, Senior International Issues Analyst, U.S. Codex Office, Office of the Under Secretary for Trade and Foreign Agricultural Affairs, by email at:

Ken.Lowery@usda.gov. For further information about the public meeting, contact the U.S. Codex Office by email at: uscodex@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Codex Alimentarius Commission was established in 1963 by two United Nations organizations: the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure fair practices in the food trade; promotes coordination of all food standards work undertaken by international governmental and nongovernmental organizations; determines priorities, initiates, and guides the preparation of draft standards; finalizes the standards elaborated and publishes them in the Codex Alimentarius (food code) either as regional or worldwide standards, wherever this is practicable; and amends published standards, as appropriate, in the light of new developments.

Issues To Be Discussed at the Public Meeting

The following items on the agenda for the 47th Session of CAC will be discussed during the public meeting:

- Report by the Chairperson on the 86th and 87th Sessions of the Executive Committee (including matters referred)
- Amendments to the Procedural Manual
- Work of Codex Committees (adoption, new work, revocation, discontinuation, and amendments to Codex texts proposed by the following committees):
 - Codex Committee on Spices and Culinary Herbs
 - Codex Committee on Fats and Oils
 - Codex Committee on Food Hygiene
 - Codex Committee on Contaminants in Foods
 - Codex Committee on Food Additives
 - Codex Committee on Methods of Analysis and Sampling
 - Codex Committee on Pesticide Residues
 - FAO/WHO Coordinating Committee for Latin American and the Caribbean
 - Codex Committee on Food Import and Export Inspection and Certification Systems

- Codex Committee on Nutrition and Foods for Special Dietary Uses
 - Codex Committee on Fish and Fishery Products
 - Codex Committee on Residues of Veterinary Drugs in Foods
 - Codex Committee on Food Labelling
 - Proposals for new work
 - Other Matters Relating to Codex Subsidiary Bodies
 - Editorial Amendments to Codex texts proposed by the Codex Secretariat
 - Codex Budgetary and Financial Matters
 - Reports of the FAO/WHO Coordinating Committees
 - Codex Strategic Plan 2020 to 2025, Implementation Report 2022 to 2023
 - Codex Strategic Plan 2026 to 2031
 - Matters Arising from FAO/WHO
 - Potential Webcasting of the Executive Committee
 - Election of the Chairperson and Vice-Chairpersons, Members of the Executive Committee Elected on a Geographical Basis, and Appointment of Coordinators
 - Designation of Countries Responsible for Appointing the Chairpersons of Codex Subsidiary Bodies
 - Other Business
 - Adoption of the Report
- Relevant documents are or will be available at the following address:
<https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CAC&session=47>.

Public Meeting

At the November 14, 2024, public meeting, draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to Ken.Lowery@usda.gov and uscodex@usda.gov. Written comments should state that they relate to activities of the 47th Session of CAC.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, the U.S. Codex Office will announce this **Federal Register** publication on-line through the USDA Codex web page located at: <http://www.usda.gov/codex>, a link that also offers an email subscription service providing access to information related to Codex. Customers can add or delete their subscriptions themselves and have the option to password protect their accounts.

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How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at <https://www.usda.gov/oascr/filing-program-discrimination-complaint-usda-customer>, or write a letter signed by you or your authorized representative. Send your completed complaint form or letter to USDA by mail, fax, or email. Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250-9410; Fax: (202) 690-7442; Email: program.intake@usda.gov. Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done at Washington, DC, on October 7, 2024.

Julie A. Chao,

Deputy U.S. Manager for Codex Alimentarius.

[FR Doc. 2024-23454 Filed 10-9-24; 8:45 am]

BILLING CODE 3420-3F-P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request To Conduct a New Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to seek approval to conduct a new information collection to gather data related to the use of agroforestry practices.

DATES: Comments on this notice must be received by December 9, 2024 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535-0273, by any of the following methods:

- *Email:* ombofficer@nass.usda.gov. Include docket number above in the subject line of the message.
 - *E-fax:* 855-838-6382.
 - *Mail:* Mail any paper, disk, or CD-ROM submissions to: Richard Hopper, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336, South Building, 1400 Independence Avenue SW, Washington, DC 20250-2024.
 - *Hand Delivery/Courier:* Hand deliver to: Richard Hopper, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336, South Building, 1400 Independence Avenue SW, Washington, DC 20250-2024.
- FOR FURTHER INFORMATION CONTACT:** Joseph J. Prusacki, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, 202-720-2707. Copies of this information collection and related instructions can be obtained without charge from Richard Hopper, NASS—OMB Clearance Officer, at 202-720-2206 or at ombofficer@nass.usda.gov.

SUPPLEMENTARY INFORMATION:

Title: Cooperator Funded Chemical Use Surveys.

OMB Control Number: 0535-0273.

Expiration Date of Approval: May 31, 2025.

Type of Request: Intent to Seek Approval to Revise and Extend an Information Collection for a period of three years.

Abstract: The chemical use data collection activities in this clearance request would be conducted through cooperative agreements with State departments of agriculture, land-grant universities, or other organizations with which NASS has a Memorandum of Understanding (MOU). Previously, these collections were included in the Agricultural Resource Management and Chemical Use Surveys ICR (0535-0218). These chemical use surveys are being separated out to allow flexibility for survey changes and possible new surveys without affecting the surveys funded through USDA's Congressional appropriation.

Authority: These data will be collected under authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-113, 44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at

5 CFR part 1320. All NASS employees and NASS contractors must also fully comply with all provisions of the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2018, title III of Public Law 115–435, codified in 44 U.S.C. ch. 35. CIPSEA supports NASS's pledge of confidentiality to all respondents and facilitates the agency's efforts to reduce burden by supporting statistical activities of collaborative agencies through designation of NASS agents, subject to the limitations and penalties described in CIPSEA.

Estimate of Burden: Public reporting burden for this collection of information varies for the surveys in this information collection request, but overall will average 35 minutes per response. NASS plans to mail out publicity materials with the questionnaires to inform respondents of the importance of this survey. NASS will also use mailing and internet data collection tools, followed up with phone and limited personal enumeration of non-respondents to increase response rates and to minimize data collection costs.

Respondents: Farmers and Ranchers.

Estimated Number of Respondents: 19,500.

Estimated Total Annual Burden on Respondents: 11,400 hours.

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 will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological, or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, September 13, 2024.

Joseph J. Prusacki,

Associate Administrator.

[FR Doc. 2024–23452 Filed 10–9–24; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 this notice announces the intention of the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection, the custom works surveys. This clearance allows NASS to conduct custom works surveys in a timely manner for the cooperating institutions providing funding for the surveys. There will be no revision to annual burden hours for the surveys.

DATES: Comments on this notice must be received by December 9, 2024 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0266, by any of the following methods:

- *Email:* ombofficer@nass.usda.gov. Include docket number above in the subject line of the message.
- *E-fax:* 855–838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: Richard Hopper, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336, South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

• *Hand Delivery/Courier:* Hand deliver to: Richard Hopper, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336, South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT:

Joseph J. Prusacki, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, 202–720–2707. Copies of this information collection and related instructions can be obtained without charge from Richard Hopper, NASS—OMB Clearance Officer, at 202–720–2206 or at ombofficer@nass.usda.gov.

SUPPLEMENTARY INFORMATION:

Title: Custom Works Surveys.

OMB Control Number: 0535–0266.

Expiration Date of Approval: May 31, 2025.

Type of Request: Intent to Seek Approval to Revise and Extend an Information Collection for a period of three years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to collect, prepare, and issue state and national estimates of crop and livestock production, prices, and disposition; as well as economic statistics, environmental statistics related to agriculture; and also to conduct the Census of Agriculture.

The Custom Works program will survey farmers who potentially paid for custom services during a specified reference period to collect information on how much they paid for those services. These services include land tillage, application of fertilizers and chemicals, planting, harvesting, hauling, various livestock tasks, and many more tasks. The program will provide farm operators with estimates of the average prices paid for different custom services in their state and/or local area. All questionnaires included in this information collection will be voluntary. This project is conducted as a cooperative effort between NASS and state agricultural departments and/or universities. Funding will be provided by the cooperating institutions under full cost recovery. The time between when funding for an individual survey is secured and the desired start of data collection is expected often to be too short to allow for a separate OMB approval for each survey. With this request, NASS will be able to provide services in a timelier manner.

Authority: These data will be collected under authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–113, 44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320. All NASS employees and NASS contractors must also fully comply with all provisions of the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2018, title III of Public Law 115–435, codified in 44 U.S.C. ch. 35. CIPSEA supports NASS's pledge of confidentiality to all respondents and facilitates the agency's efforts to reduce burden by supporting statistical activities of collaborative agencies through designation of NASS agents, subject to the limitations and penalties described in CIPSEA.

Estimate of Burden: Public reporting burden for this information collection is based on similar surveys with expected

response time of 20 minutes. The estimated sample size will be approximately 42,000. The frequency of data collection for each survey is as needed by the cooperating institution. The estimated number of responses per respondent is 1. Publicity materials and instruction sheets will account for approximately 5 minutes of additional burden per respondent. Respondents who refuse to complete a survey will be allotted 2 minutes of burden per attempt to collect the data.

Respondents: Farmers who potentially paid for custom services during the reference period.

Estimated Number of Respondents: 42,000.

Frequency of Responses: On occasion.

Estimated Total Burden on

Respondents: 16,000 hours.

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 will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological, or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, September 13, 2024.

Joseph J. Prusacki,
Associate Administrator.

[FR Doc. 2024-23451 Filed 10-9-24; 8:45 am]

BILLING CODE 3410-20-P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

[Docket No.: RUS-24-ELECTRIC-0027]

60-Day Notice of Proposed Information Collection: Electric Engineering, Architectural Services and Design Policies and Procedures; OMB Control No.: 0572-0118

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Utilities

Service (RUS) intention to request a revision of a currently approved information collection and invites comments on this information collection.

DATES: Comments on this notice must be received by December 9, 2024, to be assured of consideration.

ADDRESSES: Comments may be submitted through the Federal eRulemaking Portal: Go to <http://www.regulations.gov> and, in the "Search Field" box, labeled "Search for dockets and documents on agency actions," enter the following docket number: (RUS-24-ELECTRIC-0027), and click "Search." To submit public comments, select the "Comment" button. Before inputting your comments, you may also review the "Commenter's Checklist" (optional). Insert your comments under the "Comment" title, click "Browse" to attach files (if applicable). Input your email address and select an identity category then click "Submit Comment."

Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's "FAQ" link.

FOR FURTHER INFORMATION CONTACT:

MaryPat Daskal, Chief, Branch 1, Rural Development Innovation Center—Regulations Management Division, U.S. Department of Agriculture, 1400 Independence Avenue SW, STOP 1522, South Building, Washington, DC 20250-1522. Telephone: (202) 720-7853. Email: MaryPat.Daskal@usda.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an existing information collection that the Agency is submitting to OMB for revision.

Title: 7 CFR part 1724 and 1738, Electric Engineering, Architectural Services and Design Policies and Procedures.

OMB Control Number: 0572-0118.

Expiration Date of Approval: January 31, 2025.

Type of Request: Revision of a currently approved collection.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 2 hours per response.

Respondents: Businesses, not-for-profit institutions and others.

Estimated Number of Respondents: 4.

Estimated Number of Responses per Respondent: 1.

Estimated Number of Responses: 4.

Estimated Total Annual Burden on Respondents: 8 hours.

Abstract: The Agency requires borrowers to use standard contract forms under certain circumstances. The use of standard forms helps assure the Agency that appropriate standards and specifications are maintained, that the Agency's loan security is not adversely affected, and that loan and loan guarantee funds are used effectively and for the intended purpose. Standardization of forms by the Agency results in substantial savings to Borrowers. If standard forms were not used, borrowers would be required to prepare documents, and the government would require extensively and costly review by both the Agency and the Office of General Counsel. The contract forms included in this collection of information are RUS Form 211, "Engineering Service Contract for the Design and Construction of a Generating Plant," RUS Form 220, "Architectural Services Contract," and RUS Form 236, "Engineering Service Contract, "Electric System Design and Construction."

Comments are invited on: (a) whether this collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques, or other forms of information technology.

Copies of this information collection can be obtained from Kimble Brown, Rural Development Innovation Center, Regulations Management Division, at Kimble.brown@usda.gov. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Andrew Berke,
Administrator, Rural Utilities Service.

[FR Doc. 2024-23484 Filed 10-9-24; 8:45 am]

BILLING CODE 3410-15-P

DEPARTMENT OF AGRICULTURE**Rural Utilities Service****[Docket No. RUS-24-ELECTRIC-0026]****60-Day Notice of Proposed Information Collection: Electric System Construction Policies and Procedures; OMB Control No.: 0572-0107****AGENCY:** Rural Utilities Service, USDA.**ACTION:** Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Utilities Service (RUS) intention to request a revision of a currently approved information collection and invites comments on this information collection.

DATES: Comments on this notice must be received by December 9, 2024, to be assured of consideration.

ADDRESSES: Comments may be submitted through the Federal eRulemaking Portal: Go to <http://www.regulations.gov> and, in the "Search Field" box, labeled "Search for dockets and documents on agency actions," enter the following docket number: (RUS-24-ELECTRIC-0026), and click "Search." To submit public comments, select the "Comment" button. Before inputting your comments, you may also review the "Commenter's Checklist" (optional). Insert your comments under the "Comment" title, click "Browse" to attach files (if applicable). Input your email address and select an identity category then click "Submit Comment." Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's "FAQ" link.

FOR FURTHER INFORMATION CONTACT:

MaryPat Daskal, Chief, Branch 1, Rural Development Innovation Center—Regulations Management Division, U.S. Department of Agriculture, 1400 Independence Avenue SW, STOP 1522, South Building, Washington, DC 20250-1522. Telephone: (202) 720-7853. Email: MaryPat.Daskal@usda.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an

information collection that RUS is submitting to OMB for revision.

Title: 7 CFR 1726, Electric System Construction Policies and Procedures.

OMB Control Number: 0572-0107.

Expiration Date of Approval: January 31, 2025.

Type of Request: Revision of a currently approved collection.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .025 hours per response.

Respondents: Businesses or other for profits; Not-for-profit institutions.

Estimated Number of Respondents: 477.

Estimated Number of Responses per Respondent: 6.9.

Estimated number of Total Responses: 3,319.

Estimated Total Annual Burden on Respondents: 82 hours.

Abstract: To facilitate the programmatic interest of the Rural Electrification Act of 1936, 7 U.S.C. 901, *et seq.* (RE Act), and, in order to assure that loans made or guaranteed by RUS are adequately secured, RUS, as a secured lender, has established certain standards and specifications for materials, equipment, and construction of electric systems. The use of standard forms, construction contracts, and procurement procedures helps assure that appropriate standards and specification are maintained, that RUS' loan security is not adversely affected, and the loan and loan guarantee funds are used effectively and for the intended purposes. The list of forms and corresponding purposes for this information collection are as follows:

1. RUS Form 168b, Contractor's Bond. This form is used to provide a surety bond for contracts on RUS Forms 200, 257, 786, 790, & 830.

2. RUS Form 168c, Contractor's Bond (less than \$1 million). This form is used to provide a surety bond in lieu of RUS Form 168b, when contractor's surety has accepted a small business administration guarantee.

3. RUS Form 187, Certificate of Completion-Contract Construction. This form is used for the closeout of RUS Forms 200, 257, 786, and 830.

4. RUS Form 198, Equipment Contract. This form is used for equipment purchases.

5. RUS Form 200, Construction Contract-Generating. This form is used for generating plant construction or for the furnishing and installation of major items of equipment.

6. RUS Form 213, Certificate ("Buy American"). This form is used to document compliance with the "Buy American" requirement.

7. RUS Form 224, Waiver and Release of Lien. This form is used by subcontractors to provide a release of lien in connection with the closeout of RUS Forms 198, 200, 257, 786, 790, and 830.

8. RUS Form 231, Certificate of Contractor. This form is used for the closeout of RUS Forms 198, 200, 257, 786, and 830.

9. RUS Form 238, Construction or Equipment Contract Amendment. This form is used to amend contracts except for distribution line construction contracts.

10. RUS Form 254, Construction Inventory. This form is used to document the final construction in connection with the closeout of RUS Form 830.

11. RUS Form 257, Contract to Construct Buildings. This form is used to construct headquarter buildings, generating plant buildings, and other structure construction.

12. RUS Form 307, Bid Bond. This form is used to provide a bid bond in RUS Forms 200, 257, 786, 790 and 830.

13. RUS Form 786, Electric System Communications and Control Equipment Contract. This form is used for delivery and installation of equipment for system communications.

14. RUS Form 790, Electric System Construction Contract Non-Site Specific Construction (Notice and Instructions to Bidders). This form is used for limited distribution construction accounted for under work order procedure.

15. RUS Form 792b, Certificate of Contractor and Indemnity Agreement (Line Extensions). This form is used in the closeout of RUS Form 790.

16. RUS Form 830, Electric System Construction Contract (labor & material). This form is used for distribution and/or transmission project construction.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the collection including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Copies of this information collection can be obtained from Kimble Brown, Rural Development Innovation Center,

Regulations Management Division, at Kimble.brown@usda.gov. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Andrew Berke,

Administrator, Rural Utilities Service.

[FR Doc. 2024–23477 Filed 10–9–24; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

[Docket No.: RUS–24–AGENCY–0028]

60-Day Notice of Proposed Information Collection: Special Authority To Enable Funding of Broadband and Smart Utility Facilities Across Select Rural Development Programs (Smart Utility); OMB Control No.: 0572–0156

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces Rural Development's (RD) intention to request a revision of a currently approved information collection and invites comments on this information collection.

DATES: Comments on this notice must be received by December 9, 2024, to be assured of consideration.

ADDRESSES: Comments may be submitted through the Federal eRulemaking Portal: Go to <http://www.regulations.gov> and, in the "Search Field" box, labeled "Search for dockets and documents on agency actions," enter the following docket number: (RUS–24–AGENCY–0028), and click "Search." To submit public comments, select the "Comment" button. Before inputting your comments, you may also review the "Commenter's Checklist" (optional). Insert your comments under the "Comment" title, click "Browse" to attach files (if applicable). Input your email address and select an identity category then click "Submit Comment." Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's "FAQ" link.

FOR FURTHER INFORMATION CONTACT:

MaryPat Daskal, Chief, Branch 1, Rural Development Innovation Center—Regulations Management Division, U.S. Department of Agriculture, 1400 Independence Avenue SW, STOP 1522, South Building, Washington, DC 20250–

1522. Telephone: (202) 720–7853.

Email: MaryPat.Daskal@usda.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an existing information collection that the Agency is submitting to OMB for revision.

Title: 7 CFR 1980, Special Authority to Enable Funding of Broadband and Smart Utility Facilities Across Select Rural Development Programs (Smart Utility).

OMB Control Number: 0572–0156.

Expiration Date of Approval: January 31, 2025.

Type of Request: Revision of a currently approved collection.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 1.5 hours per response.

Respondents: Businesses, not-for-profit institutions, and others.

Estimated Number of Respondents: 20.

Estimated Number of Responses per Respondent: 7.95.

Estimated Number of Responses: 159.

Estimated Total Annual Burden on Respondents: 239 hours.

Abstract: The collection of information is necessary for RD to determine an applicant's ability to borrow under the terms of the 2018 Farm Bill and included programs and that the applicant complies with statutory, regulatory, and administrative eligibility requirements for loan assistance. As part of that submission, applicants are required to provide a service area map, where applicable, of their entire service territory.

Applicants seeking funding to finance the provision of retail broadband under the special broadband authority of this part are generally expected to comply with the rules related to broadband funding under Title VI of the Rural Electrification Act. To be considered for funding under special broadband authority, applicants must provide:

- (1) A description of the proposed retail broadband project;
- (2) a map, where applicable, of the proposed service area to be funded under smart utility authority of the applicant;
- (3) the amount and type of support requested by the applicant;

(4) any other information required of similar applicants under Title VI of the Rural Electrification Act.

Fully Searchable Data Base—The applicant information provided will be made part of a fully searchable database which could disclose to the public the information above.

Public Notice Survey—The agency will post a public notice filing on the agency's website. Incumbent service providers in the area may respond to the public notice filing by providing a public notice response.

Comments are invited on: (a) whether this collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques, or other forms of information technology.

Copies of this information collection can be obtained from Kimble Brown, Rural Development Innovation Center, Regulations Management Division, at Kimble.Brown@usda.gov. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Andrew Berke,

Administrator, Rural Utilities Service.

[FR Doc. 2024–23490 Filed 10–9–24; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–844]

Narrow Woven Ribbons With Woven Selvage From Taiwan: Preliminary Results and Rescission, in Part, of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that narrow woven ribbons with woven selvage (ribbons) from Taiwan were sold in the United States at less than normal value (NV) during the

period of review (POR), September 1, 2022, through August 31, 2023. Additionally, Commerce is rescinding this administrative review, in part, with respect to certain companies for which requests for review were timely withdrawn. We invite interested parties to comment on these preliminary results.

DATES: Applicable October 10, 2024.
FOR FURTHER INFORMATION CONTACT: Paul Senoyuit, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-6106.

SUPPLEMENTARY INFORMATION:

Background

On September 1, 2010, Commerce published in the **Federal Register** the antidumping duty order on ribbons from Taiwan.¹ On September 6, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order* for the POR.² On November 15, 2023, based on timely requests for review by Berwick Offray LLC and its wholly-owned subsidiary Lion Ribbon Company, LLC (the petitioners), and in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the *Order* covering 59 exporters and/or producers.³ On January 26, 2024, the petitioners withdrew their request for an administrative review with respect to all companies for which Commerce initiated a review other than Hao Shyang Ind. Co. Ltd. (Hao Shyang) and Lung Che Ribbons Enterprises Co. Ltd. (Lung Che).⁴ On May 10, 2024, Commerce extended the time period for issuing the preliminary results of this review until September 27, 2024.⁵ On

¹ See *Narrow Woven Ribbons with Woven Selvedge from Taiwan and the People's Republic of China: Antidumping Duty Orders*, 75 FR 53632 (September 1, 2010); see also *Narrow Woven Ribbons with Woven Selvedge from Taiwan and the People's Republic of China: Amended Antidumping Duty Orders*, 75 FR 56982, 56985 (September 17, 2010) (collectively, *Order*).
² See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation: Opportunity To Request Administrative Review and Join Annual Inquiry Service List*, 88 FR 60923 (September 6, 2023).
³ See Petitioners' Letter, "Request for Administrative Review," dated September 28, 2023; see also *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 88 FR 78298 (November 15, 2023) (*Initiation Notice*).
⁴ See Petitioners' Letter, "Withdrawal of Administrative Review Request as to Certain Companies," dated January 26, 2024 (Withdrawal of Review Request) at 1 and Appendix 1.
⁵ See Memorandum, "Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review," dated May 10, 2024.

July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.⁶ The deadline for the preliminary results is now October 4, 2024. For a complete description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum.⁷

Scope of the Order

The products subject to the *Order* are narrow woven ribbons with woven selvedge from Taiwan. For a complete description of the scope of the *Order*, see the Preliminary Decision Memorandum.⁸

Methodology

Commerce is conducting this review in accordance with sections 751(a)(1)(B) and (2) of the Tariff Act of 1930, as amended (the Act). Pursuant to sections 776(a) and (b) of the Act, Commerce preliminarily relied entirely upon facts otherwise available with adverse inferences for Hao Shyang and Lung Che. For a complete description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached in Appendix I of this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum is available at <https://access.trade.gov/public/FRNotices/ListLayout.aspx>.

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 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 January 26, 2024, the petitioners timely withdrew their request for an administrative review with respect to all companies for which a review was requested other than Hao Shyang and

⁶ See Memorandum, "Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings," dated July 22, 2024.
⁷ See Memorandum, "Decision Memorandum for the Preliminary Results Administrative Review of the Antidumping Duty Order on Narrow Woven Ribbons with Woven Selvedge from Taiwan; 2022-2023," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).
⁸ *Id.*

Lung Che.⁹ Accordingly, because no other parties requested a review of these companies, we are rescinding this administrative review, in part, with respect to the 57 companies listed in Appendix II. The administrative review remains active with respect to the mandatory respondents, Hao Shyang and Lung Che.

Preliminary Results of Review

Commerce preliminarily determines that the following estimated weighted-average dumping margin exists for the period September 1, 2022, through August 31, 2023:

Producer or exporter	Weighted-average dumping margin (percent)
Hao Shyang Ind. Co. Ltd	137.20
Lung Che Ribbons Enterprises Co. Ltd	137.20

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a preliminary results finding within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of preliminary results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied total adverse facts available (AFA) to the two individually examined companies subject to this review, in accordance with section 776 of the Act, there are no calculations to disclose.

Public Comment

Interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.¹⁰ Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.¹¹ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹²
As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior

⁹ See Withdrawal of Review Request.
¹⁰ See 19 CFR 351.309(c)(ii); see also 19 CFR 351.303 (for general filing requirements).
¹¹ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).
¹² See 19 CFR 351.309(c)(2) and (d)(2).

proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.¹³ Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹⁴

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, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of issues to be discussed. If a request for a hearing is made, Commerce intends to hold a hearing at a time and date to be determined.¹⁵ Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date. All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed using ACCESS.¹⁶ An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act, upon completion of the final results of 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.¹⁷

For the companies for which this review is being rescinded, in part, Commerce will instruct CBP to assess antidumping duties on all appropriate entries. Antidumping duties shall be assessed at rates equal to the cash deposit rate for estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). With respect to the rescission of this review, in part, Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of this notice in the **Federal Register**.

For companies subject to this 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

The following cash deposit requirements will be effective upon publication in the **Federal Register** of the notice of final results of administrative review for all shipments of ribbons from Taiwan entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Hao Shyang and Lung Che will be equal to the weighted-average dumping margin established in the final results of this review; (2) for merchandise exported by a company not covered in this review but covered in a prior completed segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published in the completed segment for the most recent period; (3) if the exporter is not a firm covered in this review or another completed segment of this proceeding, but the producer is, then the cash deposit rate will be the company-specific rate established for the completed segment for the most recent period for the producer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 4.37 percent, the all-others rate determined in the less-than-fair-value investigation.¹⁸ These cash deposit

requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless the deadline is otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised by interested parties in written briefs, within 120 days after the date of publication of this notice in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

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 and/or countervailing 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 and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of countervailing duties.¹⁹

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h) and 351.221(b)(4).

Dated: October 3, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations performing the non-exclusive functions and duties of the 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 Review, in Part
- V. Discussion of the Methodology
- VI. Recommendation

Appendix II

Companies Rescinded From Review

1. A-MADEUS TEXTILE LTD.
2. A-MEN Ribbons Co., Ltd.
3. Antonio Proietti Int. Inc.
4. Apex Trimmings
5. Banduoo Ltd.
6. Bon-Mar Textiles
7. Chang Store Co. Ltd
8. Cheng Hsing Ribbon Factory

¹³ We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹⁴ See *APO and Service Final Rule*.

¹⁵ See 19 CFR 351.310(d).

¹⁶ See 19 CFR 351.303.

¹⁷ See 19 CFR 351.212(b)(1).

¹⁸ See *Order*.

¹⁹ See 19 CFR 351.402(f)(3).

9. Cheng Mei Label Mfg. Corp.
10. Christmas Castle International Ltd.
11. Dear Year Brothers Mfg. Co., Ltd
12. Dearclobber International Co Ltd
13. Ethel Enterprise Co., Ltd.; Glory Young Enterprise Co., Ltd.; King Young Enterprises Co., Ltd.
14. Everwin Textile Corp.
15. Fist Labeling Corp.
16. Friend Chiu Co., Ltd.
17. Fujian Rongshu Industry Co., Ltd.
18. Golden State Industrial Co. Ltd.
19. Great Texture Int'l Co., Ltd.
20. Guangzhou Complacent Weaving Co., Ltd.
21. Gyrostate Corp.
22. Hen Hao Trading Co. Ltd; Taiwan Tulip Ribbons and Braids Co. Ltd.
23. Hsien Chan Enterprise Co., Ltd.; Novelty Handicrafts Co., Ltd.; Shienq Huang Enterprise Co., Ltd.
24. Hubscher Ribbon Corp., Ltd.; Hubschercorp
25. Imprimerie Mikan Inc.
26. J.S. (Just Splendid) Co., Ltd.
27. JCBen Enterprises Co. Ltd.
28. Junmay Label Mfg Corp.
29. L'Emballage Tout
30. Lace Fashions Industrial Co. Ltd.
31. Linset Enterprises Co., Ltd.
32. Maple Ribbon Co., Ltd.
33. Maxtend Industry Corporation
34. May Favor Enterprise Co., Ltd
35. Ming Wei Co., Ltd.
36. Multicolor
37. N.K. Galleria Inc.
38. Nien Chow Industrial Co.
39. Pansy Weaving Co/Ltd
40. Papillon Ribbon & Bow (Canada)
41. Papillon Ribbon & Bow (H.K.) Ltd.
42. Papillon Ribbon & Bow (Shanghai) Ltd.
43. Pearl Ribbons and Trims, Inc.
44. Ren Her Industry Co. Ltd.
45. Ribbon City Company
46. Roung Shu Industry Corporation
47. Rubans G A R Inc. (Les)
48. Trio Co., Ltd
49. Trydent Co. Ltd.
50. Tse Tien Shin Enterprise Co Ltd
51. Tsong Jiaw Enterprise Co., Ltd.
52. Wing Hung (Tw) Co Ltd
53. Xiamen Especial Industrial Co., Ltd.
54. Xiamen Yi-He Textile Co., Ltd.
55. Yanzhou Bepak Gifts & Crafts Co.
56. Yih Jenq Textile Co. Ltd.
57. Yu Shin Development Co. Ltd.

[FR Doc. 2024–23443 Filed 10–9–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–469–822]

Methionine From Spain: Preliminary Results of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily

determines that the sole respondent under review, Adisseo España S.A. (Adisseo España), sold subject merchandise at less than normal value during the period of review (POR) September 1, 2022, through August 31, 2023. We invite interested parties to comment on the preliminary results of this review.

DATES: Applicable October 10, 2024.

FOR FURTHER INFORMATION CONTACT: Elizabeth Bremer, 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) 482–4987.

SUPPLEMENTARY INFORMATION:

Background

On September 14, 2021, Commerce published the antidumping duty (AD) order on methionine from Spain.¹ On September 6, 2023, Commerce notified interested parties of the opportunity to request an administrative review of the *Order* covering the POR.²

On November 15, 2023, based on timely requests for review,³ Commerce initiated an administrative review of the *Order* with respect to Adisseo España.⁴ On May 10, 2024, Commerce extended the deadline for issuing the preliminary results of this review until September 27, 2024, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act).⁵ On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.⁶ The deadline for these preliminary results are now October 4, 2024. For a complete description of the events that occurred subsequent to initiation of the review, *see* the Preliminary Decision Memorandum.⁷

¹ *See Methionine from Japan and Spain: Antidumping Duty Orders*, 86 FR 51119 (September 14, 2021) (*Order*).

² *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List*, 88 FR 60923 (September 6, 2023).

³ *See* Adisseo España's Letter, "Adisseo España S.A. and Adisseo USA Inc.'s Request for Administrative Review," dated September 29, 2023; *see also* Petitioner's Letter, "Request for Administrative Review," dated September 29, 2023.

⁴ *See Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 88 FR 78298, 78300 (November 15, 2023).

⁵ *See* Memorandum, "Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review," dated May 10, 2024.

⁶ *See* Memorandum, "Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings," dated July 22, 2024.

⁷ *See* Memorandum, "Decision Memorandum for Preliminary Results of the 2022–2023 Administrative Review of the Antidumping Duty Order on Methionine from Spain," dated

Scope of the Order⁸

The merchandise covered by the *Order* is methionine from Spain. For a full description of the scope, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. We calculated constructed export price in accordance with section 772 of the Act and normal value in accordance with section 773 of the Act.

For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is in the appendix to this notice. The Preliminary Decision Memorandum is a public document that is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Preliminary Results of Review

Commerce preliminarily finds that the following weighted-average dumping margin exists for the period September 1, 2022, through August 31, 2023:

Producer/exporter	Weighted-average dumping margin (percent)
Adisseo España S.A	0.71

Disclosure

Commerce intends to disclose under administrative protective order its calculations and analysis performed to interested parties 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 to Commerce via ACCESS no later than 30 days after the date of publication of these preliminary results of review in the **Federal Register**.⁹ Rebuttal briefs, limited to issues raised in the case briefs, may be filed in ACCESS not later

concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁸ *See Order*, 86 FR at 51120–21.

⁹ *See* 19 CFR 351.309(c)(1)(ii).

than five days after the date for filing case briefs.¹⁰ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹¹

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.¹² Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹³

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request for a hearing to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS, by no later than 5 p.m. Eastern Time within 30 days after the date of publication of this notice in the **Federal Register**. Hearing requests should contain: (1) the party's name, address, and telephone number; (2) the number of persons from the party attending the hearing; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those issues raised in the respective case briefs. If a hearing is requested, Commerce will announce the date and time of the hearing. Parties should confirm the date and time of the hearing two days before the scheduled hearing date.

Final Results of Review

Commerce intends to issue the final results of this administrative review, which will include the results of its

analysis of issues raised in the case and rebuttal briefs, within 120 days of publication of these preliminary results of review in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act, unless extended.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), upon completion of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by this review.¹⁴ If Adisseo España's weighted-average dumping margin in the final results of this review is not zero or *de minimis* (i.e., less than or equal to 0.5 percent), we will calculate importer-specific *ad valorem* assessment rates for the merchandise by dividing the total amount of dumping calculated for all reviewed sales to the importer by the total entered value of the merchandise sold to the importer.¹⁵ Where either Adisseo España'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* in the final results of review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.¹⁶

In accordance with Commerce's "automatic assessment" practice, for entries of subject merchandise during the POR produced by Adisseo España for which it did not know was destined for the United States, we intend to instruct CBP to liquidate those entries at the all-others rate (i.e., 37.53 percent)¹⁷ in the original less-than-fair-value (LTFV) investigation if there is no rate for the intermediate company(ies) involved in the transaction.¹⁸

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, Commerce 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 in effect for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the notice of the final results of this administrative review in the **Federal Register**, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Adisseo España will be equal to the weighted-average dumping margin established for Adisseo España in the final results of this administrative review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), then the cash deposit rate will be zero; (2) for exporters not covered in this review but that were previously reviewed or investigated in a prior segment of this proceeding, the cash deposit rate will continue to be the rate assigned to the company in the most recently-completed segment of this proceeding in which the producer or exporter was examined; (3) if the exporter of the subject merchandise does not have a company-specific rate but the producer of the subject merchandise does, then the cash deposit rate will be the rate assigned to the producer of the subject merchandise in the most recently completed segment of this proceeding in which the producer was examined; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 37.53 percent that was established in the investigation in this proceeding.¹⁹ These 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) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(1) and

¹⁴ See 19 CFR 351.212(b)(1).

¹⁵ *Id.*

¹⁶ See 19 CFR 351.106(c)(2); see also *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification*, 77 FR 8101, 8102 (February 14, 2012) (*Final Modification for Reviews*).

¹⁷ See *Order*, 86 FR at 51120.

¹⁸ See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

¹⁹ See *Order*, 86 FR at 51120.

¹⁰ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹¹ See 19 CFR 351.309(c)(2) and (d)(2).

¹² We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹³ See *APO and Service Final Rule*.

777(i) of the Act, and 19 CFR 351.221(b)(4).

Dated: October 4, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Discussion of the Methodology
- V. Currency Conversion
- VI. Recommendation

[FR Doc. 2024–23502 Filed 10–9–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–844]

Certain Lined Paper Products From India: Preliminary Results of Countervailing Duty Administrative Review; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies were provided to Navneet Education Limited (Navneet), a producer/exporter of certain lined paper products (lined paper) from India. The period of review (POR) is January 1, 2022, through December 31, 2022. Interested parties are invited to comment on these preliminary results.

DATES: Applicable October 10, 2024.

FOR FURTHER INFORMATION CONTACT: Peter Zukowski, 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) 482-0189.

SUPPLEMENTARY INFORMATION:

Background

On September 28, 2006, Commerce published the countervailing duty order on lined paper from India in the **Federal Register**.¹ On November 15, 2023, based

on timely requests for review, Commerce initiated this administrative review of the Order.² On January 18, 2024, Commerce issued the initial questionnaire to Navneet, the sole producer/exporter subject to this administrative review.³ On May 2, 2024, Commerce extended the deadline for the preliminary results of this review until September 27, 2024.⁴ On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.⁵ The deadline for the preliminary results is now October 4, 2024.

For a complete description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum.⁶ A list of topics included in the Preliminary Decision Memorandum is provided as the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Order

The product covered by the Order is lined paper from India. For a complete description of the scope of the Order, see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.*, a financial contribution by an “authority” that gives rise to a benefit to the recipient, and that the

subsidy is specific.⁷ For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following net countervailable subsidy rate exists for the POR, January 1, 2022, through December 31, 2022:

Company	Subsidy rate (percent <i>ad valorem</i>)
Navneet Education Limited ..	2.50

Disclosure

Commerce intends to disclose its calculations and analysis performed in connection with these preliminary results to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Public Comment

Because Commerce intends to address the new subsidy allegations following these preliminary results, interested parties will be notified of the deadline for the submission of case briefs at a later date.⁸ Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.⁹ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹⁰ All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their briefs that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs

² See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 88 FR 78298 (November 15, 2023).

³ See Commerce's Letter, “*Countervailing Duty Questionnaire*,” dated January 18, 2024.

⁴ See Memorandum, “*Certain Lined Paper Products from India: Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review*,” dated May 2, 2024.

⁵ See Memorandum, “*Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings*,” dated July 22, 2024.

⁶ See Memorandum, “*Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Certain Lined Paper Products from India; 2022*,” dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁷ 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.

⁸ See 19 CFR 351.309(c)(1)(ii); see also 19 CFR 351.303 (for general filing requirements).

⁹ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

¹⁰ See 19 CFR 351.309(c)(2) and (d)(2).

¹ See *Notice of Amended Final Determination of Sales at Less Than Fair Value: Certain Lined Paper Products from the People's Republic of China; Notice of Antidumping Duty Orders: Certain Lined Paper Products from India, Indonesia and the People's Republic of China; and Notice of Countervailing Duty Orders: Certain Lined Paper Products from India and Indonesia*, 71 FR 56949 (September 28, 2006) (*Order*).

a public, executive summary for each issue raised in their briefs.¹¹ Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).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, filed electronically via ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce will inform parties of the scheduled date for the hearing.¹³

Assessment Rates

Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this 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, upon publication of the final results, Commerce intends to instruct

CBP to collect cash deposits of estimated countervailing duties in the amount indicated above with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review, except where the rate calculated in the final results is zero or *de minimis*. These cash deposit instructions, when imposed, shall remain in effect until further notice.

Final Results

Unless the deadline is extended pursuant to section 751(a)(3)(a) of the Act and 19 CFR 351.213(h)(2), Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues by the parties in any written briefs, no later than 120 days after the date of publication of these preliminary results.

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 351.221(b)(4).

Dated: October 4, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Diversification of India's Economy
- V. Subsidies Valuation
- VI. Analysis of Programs
- VII. Recommendation

[FR Doc. 2024–23499 Filed 10–9–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–088]

Certain Steel Racks and Parts Thereof From the People's Republic of China: Preliminary Results and Partial Rescission of the Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that the companies under review either sold certain steel racks and parts thereof (steel racks) from the

People's Republic of China (China) in the United States at prices below normal value (NV) during the period of review (POR) September 1, 2022, through August 31, 2023, or do not qualify for a separate rate. Further, Commerce is rescinding this review with respect to six companies. Commerce invites interested parties to comment on the preliminary results of this review.

DATES: Applicable October 10, 2024.

FOR FURTHER INFORMATION CONTACT: Jonathan 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) 482–3518.

SUPPLEMENTARY INFORMATION:

Background

On September 6, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on steel racks from China.¹ After receiving review requests, Commerce initiated this review with respect to nine companies.² On May 28, 2024, Commerce extended the deadline for issuing the preliminary results of this review until September 27, 2024.³ On August 8, 2024, Commerce tolled certain deadlines in this administrative review by seven days. The deadline for the final results of this review is now October 4, 2024.⁴

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.⁵ A list of topics discussed in the Preliminary Decision Memorandum is included as an

¹ *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List*, 88 FR 60923 (September 6, 2023); *see also Certain Steel Racks and Parts Thereof from the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order; and Countervailing Duty Order*, 84 FR 48584 (September 16, 2019) (*Order*).

² *See Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 88 FR 78298 (November 15, 2023) (*Initiation Notice*).

³ *See Memorandum*, “Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,” dated May 28, 2024.

⁴ *See Memorandum*, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated August 8, 2024. Commerce notes that the tolling of certain deadlines in administrative proceedings actually occurred on July 22, 2024.

⁵ *See Memorandum*, “Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Certain Steel Racks and Parts Thereof from the People's Republic of China; 2022–2023,” dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

¹¹ We use the term “issue” here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹² *See APO and Service Procedures*.

¹³ *See* 19 CFR 351.310(d).

appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Order

The merchandise covered by the Order is steel racks from China. A full description of the scope of the Order is contained in the Preliminary Decision Memorandum.

Partial Rescission of the Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if all parties who requested a review withdraw their requests within 90 days of the date that the notice of initiation of the requested review was published in the **Federal Register**. All requests to review the following companies were timely withdrawn: (1) Nanjing Dongsheng Shelf Manufacturing Co., Ltd.; (2) Ningbo Xinguang Rack Co., Ltd.; and (3) Xiamen Luckyroc Industry Co., Ltd.⁶ Therefore, consistent with 19 CFR 351.213(d)(1), Commerce is rescinding this review with respect to Nanjing Dongsheng, Ningbo Xinguang Rack, and Xiamen Luckyroc.

Further, pursuant to 19 CFR 351.213(d)(3), it is Commerce's practice to rescind an administrative review of an antidumping duty order where it concludes that there were no suspended entries of subject merchandise during the POR.⁷ Normally, upon completion of an administrative review, the suspended entries are liquidated at the antidumping duty assessment rate for the review period.⁸ Therefore, for an administrative review 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 calculated antidumping duty assessment rate for the review period.⁹ Commerce notified all interested parties of its intent to rescind the instant review with respect to Hebei Minmetals Co., Ltd. (Hebei), Nanjing Ironstone Storage Equipment Co., Ltd. (Nanjing Ironstone), and Nanjing Kingmore Logistics Equipment Manufacturing Co., Ltd. (Nanjing Kingmore) because there were no reviewable, suspended entries of subject merchandise from these companies during the POR¹⁰ and invited interested parties to comment on Commerce's intention to rescind the review with respect to these companies.¹¹ We received no comments regarding this matter. In the absence of any suspended entries of subject merchandise from these companies during the POR, we are rescinding this administrative review of Hebei, Nanjing Ironstone, Nanjing Kingmore, in accordance with 19 CFR 351.213(d)(3).

Preliminary Affiliation and Single Entity Determination

Based on record evidence in this review, Commerce preliminarily determines that mandatory respondent Jiangsu Nova Intelligent Logistics Equipment Co., Ltd. (Jiangsu Nova) and the following companies are affiliated, pursuant to section 771(33)(E) of the Tariff Act of 1930, as amended (the Act), and that they should be treated as a single entity, pursuant to 19 CFR 351.401(f)(1)–(2): (1) Nanjing Jinshidai Storage Equipment Co., Ltd., and (2) Hebei Nova Intelligent Logistics Equipment Co., Ltd. For additional

information, see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. Commerce calculated constructed export price in accordance with section 772 of the Act. Further, because China is a non-market economy (NME) country within the meaning of section 771(18) of the Act, Commerce calculated NV in accordance with section 773(c) of the Act. For a full description of the methodology underlying our preliminary results, see the Preliminary Decision Memorandum.

Separate Rates

In all proceedings involving an NME country, Commerce maintains a rebuttable presumption that all companies are subject to government control and, thus, should be assessed a single weighted-average dumping margin unless the company can affirmatively demonstrate an absence of government control, both in law (*de jure*) and in fact (*de facto*), with respect to its exports (*i.e.*, can affirmatively demonstrate that it is eligible for a separate rate).¹² Commerce has preliminarily determined that information placed on the record by Jiangsu Nova demonstrates that this company is eligible for a separate rate.¹³

However, Commerce has preliminarily determined that Jiangsu Starshine Industry Equipment Co., Ltd. (Starshine) has not demonstrated its eligibility for a separate rate because although it timely filed a separate rate application, it was selected as a mandatory respondent and failed to respond to Commerce's questionnaire. In the *Initiation Notice*, Commerce stated that “. . . exporters and producers who submit a Separate Rate Application or Certification and subsequently are selected as mandatory respondents will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.”¹⁴ Therefore, we have not granted Starshine a separate rate and have

⁹ See, e.g., *Shanghai Sunbeauty Trading Co. v. United States*, 380 F. Supp. 3d 1328, 1337 (CIT 2019), at 12 (referring to section 751(a) of the Act, the U.S. Court of International Trade held that “[w]hile the statute does not explicitly require that an entry be suspended as a prerequisite for establishing entitlement to a review, it does explicitly state the determined rate will be used as the liquidation rate for the reviewed entries. This result can only obtain if the liquidation of entries has been suspended”; see also *Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018–2019*, 86 FR 36102 (July 8, 2021), and accompanying Issues and Decision Memorandum at Comment 4; and *Solid Fertilizer Grade Ammonium Nitrate from the Russian Federation: Notice of Rescission of Antidumping Duty Administrative Review*, 77 FR 65532 (October 29, 2012) (noting that “for an administrative review to be conducted, there must be a reviewable, suspended entry to be liquidated at the newly calculated assessment rate”).

¹⁰ See Memorandum, “Automated Commercial System Shipment Query,” dated November 30, 2023.

¹¹ See Memorandum, “Notice of Intent to Rescind Review, In Part,” dated July 16, 2024.

⁶ See Nanjing Dongsheng Shelf Manufacturing Co., Ltd.'s (Nanjing Dongsheng) Letter, “Withdraw of Request for Administrative Review,” dated February 9, 2024; United Material Handling Inc.'s (United Material) Letter, “Withdraw of Request for Administrative Review,” dated February 9, 2024; and Ningbo Xinguang Rack Co., Ltd.'s (Ningbo Xinguang Rack) and Xiamen Luckyroc Industry Co., Ltd.'s (Xiamen Luckyroc) Letter, “Withdrawal of Request for Administrative Review,” dated February 13, 2024.

⁷ See, e.g., *Certain Carbon and Alloy Steel Cut-to Length Plate from the Federal Republic of Germany: Rescission of Antidumping Administrative Review; 2020–2021*, 88 FR 4154 (January 24, 2023).

⁸ See 19 CFR 351.212(b)(1).

¹² See *Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products from the People's Republic of China*, 71 FR 53079, 53082 (September 8, 2006); see also *Final Determination of Sales at Less Than Fair Value and Final Partial Affirmative Determination of Critical Circumstances: Diamond Sawblades and Parts Thereof from the People's Republic of China*, 71 FR 29303, 29307 (May 22, 2006).

¹³ See Preliminary Decision Memorandum.

¹⁴ See *Initiation Notice*, 88 FR at 78299.

treated it as part of the China-wide entity.

The China-Wide Entity

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.¹⁵ Under this policy, 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, which includes Starshine and Jiangsu JISE Intelligent Storage Equipment Co., Ltd. (JISE),¹⁶ the entity is not under review,

and the entity's rate (*i.e.*, 144.50 percent)¹⁷ is not subject to change.

Preliminary Results of Review

Commerce preliminarily determines that the following weighted-average dumping margin exists for the period September 1, 2022, through August 31, 2023:

Exporter	Weighted-average dumping margin (percent)
Jiangsu Nova Intelligent Logistics Equipment Co., Ltd./Nanjing Jinshidai Storage Equipment Co., Ltd./Hebei Nova Intelligent Logistics Equipment Co., Ltd	10.14

Disclosure and Public Comment

Commerce intends to disclose the calculations and analysis that it performed in these preliminary results of review to parties to the proceeding within five days of any public announcement of these preliminary results or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of these preliminary results of review in the **Federal Register**. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.¹⁸ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue addressed; and (2) a table of authorities.¹⁹

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their briefs that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide, at the beginning of their briefs, a public executive summary for each issue raised in their briefs.²⁰ Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive

summaries as the basis of the comment summaries included in the issues and decision memorandum that we will issue for the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).²¹

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written hearing request to the Assistant Secretary for Enforcement and Compliance, filed electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). Requests should contain: (1) the requesting party's name, address, and telephone number; (2) the number of individuals from the requesting party that will attend the hearing and whether any of those individuals is a foreign national; and (3) a list of the issues the party intends to discuss at the hearing. Issues raised in the hearing by a party will be limited to those raised in the party's case and rebuttal briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.

Assessment Rates

In accordance with section 751(a)(2)(C) of the Act, the assessment

of antidumping duties on entries of merchandise covered by the review shall be based on the final results of this review. Therefore, upon issuance of the final results of review, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise covered by this review.²²

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these preliminary results 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).

Commerce will calculate importer or customer-specific assessment rates for the individually examined respondent, in accordance with 19 CFR 351.212(b)(1).²³ Where the respondent reported reliable entered values, Commerce will calculate importer or customer-specific *ad valorem* assessment rates by dividing the total amount of dumping calculated in the final results of this review for all reviewed U.S. sales to the importer/customer by the total entered value of the merchandise sold to the importer/customer.²⁴ Where the respondent did not report entered values, Commerce will calculate importer or customer-specific per-unit assessment rates by dividing the total amount of dumping calculated in the final results of this

¹⁵ 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).

¹⁶ The record shows no suspended POR entries for JISE, and it did not have a separate rate during the POR; thus, it remains part of the China-wide entity.

¹⁷ See *Order*, 84 FR at 48585.

¹⁸ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹⁹ See 19 CFR 351.309(c)(2) and (d)(2).

²⁰ We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

²¹ See *APO and Service Final Rule*.

²² See 19 CFR 351.212(b)(1).

²³ We applied the assessment rate calculation methodology 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 See 19 CFR 351.212(b)(1).

review for all reviewed U.S. sales to the importer/customer by the total quantity of those sales. While Commerce will calculate estimated *ad valorem* importer or customer-specific assessment rates to determine whether the per-unit assessment rates are *de minimis*, Commerce will use the per-unit assessment rates where entered values were not reported.²⁵ Where either the respondent's *ad valorem* weighted-average dumping margin is zero or *de minimis*, or an importer or customer-specific *ad valorem* assessment rate is zero or *de minimis*,²⁶ Commerce will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Pursuant to a refinement to Commerce's assessment practice, where sales of subject merchandise exported by an individually examined respondent were not reported in the U.S. sales data submitted by the respondent, but the merchandise was entered into the United States during the POR, Commerce will instruct CBP to liquidate any entries of such merchandise at the antidumping duty assessment rate for the China-wide entity.²⁷

Commerce will instruct CBP to liquidate entries of subject merchandise exported by companies that are not eligible for a separate rate and which are therefore considered to be part of the China-wide entity, at the weighted-average dumping margin for the China-wide entity, *i.e.*, 144.50 percent.²⁸

Pursuant to a refinement to Commerce's assessment practice, where sales of subject merchandise exported by an individually examined respondent were not reported in the U.S. sales data submitted by the respondent, but the merchandise was entered into the United States during the POR, Commerce will instruct CBP to liquidate any entries of such merchandise at the antidumping duty assessment rate for the China-wide entity.²⁹ Commerce will instruct CBP to liquidate entries of subject merchandise exported by the companies for which it rescinded the review at the cash deposit rate required at the time of entry.

Cash Deposit Requirements

The following cash deposit requirements will be in effect for all shipments of subject merchandise entered, or withdrawn from warehouse,

for consumption on, or after, the date of publication of the notice of the final results of this administrative review in the **Federal Register**, as provided for by section 751(a)(2)(C) of the Act: (1) for an exporter granted a separate rate 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 for the exporter (except, if the rate is *de minimis*, then a cash deposit rate of zero will be required); (2) for a previously investigated or reviewed exporter of subject merchandise not under review that has a separate rate, the cash deposit rate will continue to be the exporter's existing cash deposit rate; (3) for all China exporters of subject merchandise that do not have a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin assigned to the China-wide entity, which is 144.50 percent; and (4) for a non-China exporter of subject merchandise that does not have a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin applicable to the China exporter(s) that supplied that non-China exporter.

These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, which will include the results of its analysis of issues raised in case and rebuttal briefs, within 120 days of publication of these preliminary results of review in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping 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 and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(1) and

777(i)(1) of the Act, and 19 CFR 351.213(h)(2) and 351.221(b)(4).

Dated: October 4, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Affiliation and Single Entity Treatment
- V. Discussion of Methodology
- VI. Currency Conversion
- VII. Recommendation

[FR Doc. 2024–23486 Filed 10–9–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–870]

Certain Oil Country Tubular Goods From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that certain oil country tubular goods (OCTG) from the Republic of Korea (Korea) were sold in the United States at prices below normal value. The period of review (POR) is September 1, 2022, through August 31, 2023. Interested parties are invited to comment on these preliminary results.

DATES: Applicable October 10, 2024.

FOR FURTHER INFORMATION CONTACT:

Michael J. Heaney or Mark Flessner, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4475 or (202) 482–6312, respectively.

SUPPLEMENTARY INFORMATION:

Background

These preliminary results are made in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this administrative review on November 15, 2023.¹ On May 2,

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 88 FR 78298 (November 15, 2023).

²⁵ *Id.*

²⁶ See 19 CFR 351.106(c)(2).

²⁷ See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011), for a full discussion of this practice.

²⁸ See *Order*, 84 FR at 48586.

2024, in accordance with section 751(a)(3)(A) of the Act, Commerce extended the preliminary results of review until September 27, 2024.² On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.³ The deadline for the preliminary results of review is now October 4, 2024. For a complete description of the events that followed the initiation of this administrative review, *see* the Preliminary Decision Memorandum.⁴ A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Order⁵

The product covered by the *Order* is OCTG from Korea. For a complete description of the scope of the *Order*, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(2) of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

² See Memorandum, "Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review," dated May 2, 2024.

³ See Memorandum, "Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings," dated July 22, 2024.

⁴ See Memorandum, "Issues and Decision Memorandum for the Preliminary Results of the 2022–2023 Administrative Review of the Antidumping Duty Order on Certain Oil Country Tubular Goods from the Republic of Korea" dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁵ See *Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders; and Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value*, 79 FR 53691 (September 10, 2014) (*Order*).

Rates for Non-Examined Companies

The statute and Commerce's regulations do not address the 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 or *de minimis* margins, and any margins determined entirely under section 776 of the Act.

In this administrative review, Commerce preliminarily found a zero percent margin for NEXTEEL Co., Ltd. Therefore, the only rate that is not zero, *de minimis*, or based entirely on facts otherwise available is the rate calculated for SeAH Steel Corporation (SeAH). Consequently, the rate calculated for SeAH is also assigned as the rate for the non-individually examined companies.

Preliminary Results of Review

Commerce preliminarily finds that the following estimated weighted-average dumping margins exist:

Exporter/producer	Weighted-average dumping margin (percent)
NEXTEEL Co., Ltd	0.00
SeAH Steel Corporation	0.53
Review-Specific Rate for Non-Examined Companies:	
AJU Besteel Co., Ltd	0.53
Hyundai Steel Company	0.53
Husteel Co., Ltd	0.53
ILJIN Steel Corporation	0.53

Disclosure

Commerce intends to disclose the calculations and analysis performed for these preliminary results to interested parties within five days of public announcement of the preliminary results or, if there is no public announcement, within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Public Comment

Case briefs or other written comments may be submitted to the Assistant

Secretary for Enforcement and Compliance no later than 30 days after the date of publication of these preliminary results of review.⁶ Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.⁷ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.⁸

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this administrative review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.⁹ Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results of this review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹⁰

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 date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and

⁶ See 19 CFR 351.309(c)(ii).

⁷ See 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

⁸ See 19 CFR 351.309(c)(2) and (d)(2).

⁹ We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹⁰ See *APO and Service Final Rule*.

location of the hearing two days before the scheduled date.

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, which will include the results of its analysis of issues raised in any briefs, within 120 days of publication of these preliminary results of review, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rate

Upon issuance of the final results, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.¹¹

For any individually examined respondents whose weighted-average dumping margin is above *de minimis* (i.e., greater than or equal to 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the examined sales to that importer, and we will instruct CBP to assess antidumping duties on all appropriate entries covered by this review. For entries of subject merchandise during the POR produced by each respondent for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.¹² Where the individually-selected respondent's weighted-average dumping margin is zero or *de minimis*, or an importer-specific assessment rate is zero or *de minimis*, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For the companies which were not selected for individual review, we intend to assign an assessment rate based on the methodology described in the "Rates for Non-Examined Companies" section. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review where applicable.

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**.¹³ 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 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) of the Act: (1) the cash deposit rate for the companies listed in the final results of 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, a prior 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 5.24 percent, the all-others rate established in the less-than-fair-value investigation.¹⁴ These 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 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

These preliminary results are issued and published in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(4).

Dated: October 4, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the 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. Rates for Non-Examined Companies
- V. Affiliation
- VI. Discussion of the Methodology
- VII. Currency Conversion
- VIII. Recommendation

[FR Doc. 2024-23500 Filed 10-9-24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-580-881]

Certain Cold-Rolled Steel Flat Products From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain cold-rolled steel flat products (cold-rolled steel) from the Republic of Korea (Korea) were not made at less than normal value (NV) during the period of review (POR) September 1, 2022, through August 31, 2023. Interested parties are invited to comment on these preliminary results.

DATES: Applicable October 10, 2024.

FOR FURTHER INFORMATION CONTACT: Caroline Carroll, AD/CVD Operations, Office IX, 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 September 20, 2016, Commerce published in the **Federal Register** the antidumping duty order on cold-rolled

¹¹ See 19 CFR 351.212(b)(1).

¹² For a full discussion of this clarification, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

¹³ See *Notice of Discontinuation of Policy to Issue Liquidation Instructions After 15 Days in Applicable Antidumping and Countervailing Duty Administrative Proceedings*, 86 FR 884 (January 15, 2021).

¹⁴ See *Certain Oil Country Tubular Goods from the Republic of Korea: Notice of Court Decision Not in Harmony with Final Determination*, 81 FR 59603 (August 30, 2016).

steel from Korea.¹ On September 6, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order* for the POR.² On November 15, 2023, based on timely requests for review, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the *Order*.³ On December 20, 2023, Commerce selected Hyundai Steel Company (Hyundai) and POSCO/POSCO International Corporation (collectively, POSCO) as the mandatory respondents in this administrative review.⁴ On May 17, 2024, we extended the deadline for issuing the preliminary results of this review to September 27, 2024, in accordance with section of 751(a)(3) of the Tariff Act of 1930 (the Act), and 19 CFR 351.213(h)(2).⁵ On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.⁶ The deadline for the preliminary results is now October 4, 2024. For a complete description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum.⁷

Scope of the Order

The merchandise subject to the *Order* is cold-rolled steel from Korea. For a complete description of the scope of the *Order*, see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with sections 751(a)(1)(B) and (2) of the Act. Export price and constructed export price are calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 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 attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Rate for Non-Examined Company

The Act and Commerce's regulations do not address the establishment of a weighted-average dumping margin to be determined for 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 a market economy less-than-fair-value (LTFV) investigation, for guidance when determining the weighted-average dumping margin 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 or *de minimis* margins, and any margins determined entirely {on the basis of facts available}."

In this review, we preliminarily calculated dumping margins of zero for both of the mandatory respondents. Consistent with the U.S. Court of Appeals for the Federal Circuit's decision in *Albemarle*,⁸ and Commerce's practice,⁹ we are preliminarily applying to KG Dongbu Steel Co., Ltd. (KG Dongbu), the company not selected for individual examination in this review, a margin of zero percent, because we preliminarily calculated rates of zero percent for both mandatory respondents, Hyundai and

POSCO, pursuant to section 735(c)(5)(B) of the Act.

Preliminary Results of the Review

As a result of this review, we preliminarily determine the following estimated weighted-average dumping margins for the period of September 1, 2022, through August 31, 2023:

Producer or exporter	Weighted-average dumping margin (percent)
Hyundai Steel Company	0.00
POSCO/POSCO International Corporation	0.00
KG Dongbu Steel Co., Ltd	0.00

Disclosure and Public Comment

Commerce intends to disclose the calculations performed for these preliminary results to interested parties within five days of any public announcement or, if there is no public announcement, 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 case briefs, may be filed no later than five days after the date for filing case briefs.¹⁰ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹¹

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings, we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide, at the beginning of their briefs, a public executive summary for each issue raised in their briefs.¹² Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision

¹ See *Certain Cold-Rolled Steel Flat Products from Brazil, India, the Republic of Korea, and the United Kingdom: Amended Final Affirmative Antidumping Determinations for Brazil and the United Kingdom and Antidumping Duty Orders*, 81 FR 64432 (September 20, 2016) (*Order*).

² See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review*, 88 FR 60923 (September 6, 2023).

³ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 88 FR 78298 (November 15, 2023).

⁴ See Memorandum, "Respondent Selection," dated December 20, 2023.

⁵ See Memorandum, "Extension of Deadline for Preliminary Results of 2022–2023 Antidumping Duty Administrative Review," dated May 17, 2024.

⁶ See Memorandum, "Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings," dated July 22, 2024.

⁷ See Memorandum, "Decision Memorandum for the Preliminary Results of the 2022–2023 Administrative Review of the Antidumping Duty Order on Certain Cold-Rolled Steel Flat Products from Korea," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁸ See *Albemarle Corp. v. United States*, 821 F.3d 1345 (Fed. Cir. 2016) (*Albemarle*).

⁹ See *Certain Cold-Rolled Steel Flat Products from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2020–2021*, 87 FR 60989 (October 7, 2022).

¹⁰ See 19 CFR 351.309(d)(1); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹¹ See 19 CFR 351.309(c)(2) and (d)(2).

¹² We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹³

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, filed electronically via ACCESS, within 30 days after the date of publication of this notice. Hearing requests should contain the party's name, address, and telephone number, and a list of issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce will inform parties of the time and date for the hearing.¹⁴

Unless the deadline is extended, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2), Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in any written briefs, no later than 120 days after the date of publication of these preliminary results in the **Federal Register**.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by this review.¹⁵ If the weighted-average dumping margin for an individually examined respondent is not zero or *de minimis* (i.e., less than 0.50 percent) in the final results of this review, we will calculate importer-specific *ad valorem* assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales and the total entered value of such sales in accordance with 19 CFR 351.212(b)(1).¹⁶ For any individually examined respondent whose weighted-average dumping margin is zero or *de minimis* in the final results of review, or if an importer-specific assessment rate is zero or *de minimis*, Commerce will

instruct CBP to liquidate appropriate entries without regard to antidumping duties.¹⁷

Commerce's "automatic assessment" practice will apply to entries of subject merchandise during the POR produced by Hyundai or POSCO for which the reviewed companies did not know that the merchandise they sold to the intermediary (i.e., a reseller, trading company, or exporter) was destined for the United States.¹⁸ In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.¹⁹

For KG Dongbu, the company that was not selected for individual examination, we intend to assign an assessment rate based on the review-specific rate determined as noted in the "Rate for Companies Not Selected for Individual Examination" section, above.

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 cash deposits of estimated antidumping duties, where applicable. 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 deposit requirements will be effective upon publication in the **Federal Register** 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 above will be equal to the weighted-average dumping margin established in the final results of this administrative review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for

previously investigated or reviewed companies not covered in this review, the cash deposit rate will continue to be the company-specific cash deposit rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, a prior review, or the LTFV investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 20.33 percent, the all-others rate established in the LTFV investigation.²⁰ These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing 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 and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: October 4, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Discussion of the Methodology
- V. Currency Conversion
- VI. Recommendation

[FR Doc. 2024-23489 Filed 10-9-24; 8:45 am]

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¹³ See *APO and Service Final Rule*.

¹⁴ See 19 CFR 351.310(d).

¹⁵ See 19 CFR 351.212(b)(1).

¹⁶ See *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification*, 77 FR 8101, 8103 (February 14, 2012).

¹⁷ *Id.*, 77 FR at 8102-03; see also 19 CFR 351.106(c)(2).

¹⁸ See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

¹⁹ See *Order*.

²⁰ See *Order*.

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-908]

Sodium Hexametaphosphate From the People's Republic of China: Continuation of Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC) that revocation of the antidumping duty (AD) order on sodium hexametaphosphate (SHMP) from the People's Republic of China (China) would likely lead to the continuation or recurrence of dumping and material injury to an industry in the United States, Commerce is publishing a notice of continuation of this AD order.

DATES: Applicable October 2, 2024.

FOR FURTHER INFORMATION CONTACT:

Kabir Archuleta, 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) 482-2593.

SUPPLEMENTARY INFORMATION:**Background**

On March 19, 2008, Commerce published in the *Federal Register* the AD order on SHMP from China.¹ On February 1, 2024, the ITC instituted,² and Commerce initiated,³ the third sunset review of the *Order*, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). As a result of its review, Commerce determined that revocation of the *Order* would likely lead to the continuation or recurrence of dumping, and therefore, notified the ITC of the magnitude of the margins of dumping rates likely to prevail should the *Order* be revoked.⁴

On October 2, 2024, the ITC published its determination, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the *Order* would

likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.⁵

Scope of the Order

The merchandise subject to the *Order* is sodium hexametaphosphate (SHMP). SHMP is a water-soluble polyphosphate glass that consists of a distribution of polyphosphate chain lengths. It is a collection of sodium polyphosphate polymers built on repeating NaPO₃ units. SHMP has a P₂O₅ content from 60 to 71 percent. Alternate names for SHMP include the following: Calgon; Calgon S; Glassy Sodium Phosphate; Sodium Polyphosphate, Glassy; Metaphosphoric Acid; Sodium Salt; Sodium Acid Metaphosphate; Graham's Salt; Sodium Hex; Polyphosphoric Acid, Sodium Salt; Glass H; Hexaphos; Sodaphos; Vitrafos; and BAC-N-FOS. SHMP is typically sold as a white powder or granule (crushed) and may also be sold in the form of sheets (glass) or as a liquid solution. It is imported under heading 2835.39.5000, HTSUS. It may also be imported as a blend or mixture under heading 3824.90.3900, HTSUS. The American Chemical Society, Chemical Abstract Service (CAS) has assigned the name "Polyphosphoric Acid, Sodium Salt" to SHMP. The CAS registry number is 68915-31-1. However, SHMP is commonly identified by CAS No. 10124-56-8 in the market. For purposes of the *Order*, the narrative description is dispositive, not the tariff heading, CAS registry number or CAS name.

The product covered by the *Order* includes SHMP in all grades, whether food grade or technical grade. The product covered by the *Order* includes SHMP without regard to chain length *i.e.*, whether regular or long chain. The product covered by the *Order* includes SHMP without regard to physical form, whether glass, sheet, crushed, granule, powder, fines, or other form, and whether or not in solution.

However, the product covered by the *Order* does not include SHMP when imported in a blend with other materials in which the SHMP accounts for less than 50 percent by volume of the finished product.

Continuation of the Order

As a result of the determinations by Commerce and the ITC that revocation of the *Order* would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section

751(d)(2) of the Act, Commerce hereby orders the continuation of the *Order*. U.S. Customs and Border Protection will continue to collect AD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of the continuation of the *Order* is October 2, 2024. Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next five-year review of the *Order* not later than 30 days prior to the fifth anniversary of the date of the last determination by the Commission.

Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceedings. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This five-year (sunset) review and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act, and published in accordance with section 777(i) of the Act and 19 CFR 351.218(f)(4).

Dated: October 4, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024-23442 Filed 10-9-24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A-533-899]

Granular Polytetrafluoroethylene Resin From India: Final Results of Antidumping Duty Administrative Review; 2021-2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Gujarat Fluorochemicals Limited (GFCL) made sales of subject merchandise in the United States at prices below normal value during the

¹ See Notice of Antidumping Duty Order: Sodium Hexametaphosphate from the People's Republic of China, 73 FR 14772 (March 19, 2008) (*Order*).

² See Sodium Hexametaphosphate from China; Institution of a Five-Year Review, 89 FR 6547 (February 1, 2024).

³ See Initiation of Five-Year (Sunset) Reviews, 89 FR 6499 (February 1, 2024).

⁴ See Sodium Hexametaphosphate from the People's Republic of China: Final Results of the Expedited Third Sunset Review of the Antidumping Duty Order, 89 FR 46362 (May 29, 2024), and accompanying Issues and Decision Memorandum.

⁵ See Sodium Hexametaphosphate from China; Determination, 89 FR 80264 (October 2, 2024).

period of review (POR) September 2, 2021, through February 28, 2023.

DATES: Applicable October 10, 2024.

FOR FURTHER INFORMATION CONTACT: William Horn or Noah Wetzel, 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) 482-4868 and (202) 482-7466 respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 3, 2024, Commerce published the *Preliminary Results* and invited interested parties to comment.¹ On July 15, 2024, Commerce extended the deadline for the final results of this administrative review until September 27, 2024.² On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.³ The deadline for the final results is now October 4, 2024. For a summary of the events that occurred since the *Preliminary Results*, see the Issues and Decision Memorandum.⁴ Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order⁵

The merchandise covered by the *Order* is granular polytetrafluoroethylene resin (granular PTFE) from India. For a complete description of the scope of the *Order*, see the Issues and Decision Memorandum.

Analysis of Comments Received

We addressed all issues raised in the case and rebuttal briefs filed in this administrative review in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is in the 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/FRNNoticesListLayout.aspx>.

Changes Since the Preliminary Results

Based on our evaluation of the comments received from interested parties regarding our *Preliminary Results* and our analysis of the record, we made certain changes to the weighted-average dumping margin calculation for GFCL, as detailed in the Issues and Decision Memorandum.⁶ For a discussion of the comments, see the Issues and Decision Memorandum.

Final Results of Review

We determine that the following estimated weighted-average dumping margin exists for the period September 2, 2021, through February 28, 2023:

Exporter/producer	Weighted-average dumping margin (percent)
Gujarat Fluorochemicals Limited	2.40

Disclosure

We intend to disclose the calculations performed for these final results of review to interested parties within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

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 section 751(a)(2)(C) of the Act and 19 CFR 351.212(b). Pursuant to 19 CFR 351.212(b)(1), because GFCL reported the entered value for its U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of those sales. Where an importer-specific assessment rate is zero or *de minimis*, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

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).

Consistent with Commerce's clarification of its assessment practice, for entries of subject merchandise during the POR produced by GFCL where it 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 established in the original less-than-fair-value (LTFV) investigation of 10.01 percent *ad valorem*,⁷ if there is no rate for the intermediate company(ies) involved in the transaction.⁸

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for GFCL will be equal to the weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by a producer or exporter 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 the producer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers and exporters will continue to be 10.01 percent *ad valorem*, the all-others rate established in the LTFV investigation.⁹ These cash deposit requirements, when imposed, shall remain in effect until further notice.

⁷ See *Order*, 87 FR at 14515.

⁸ For a full discussion of this practice, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

⁹ See *Order*, 87 FR at 14515.

¹ See *Granular Polytetrafluoroethylene Resin from India: Preliminary Results of Antidumping Administrative Review*, 89 FR 22989 (April 3, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Extension of Deadline for Final Results of Antidumping Duty Administrative Review," dated July 15, 2024.

³ See Memorandum, "Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings," dated July 22, 2024.

⁴ See Memorandum, "Issues and Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order on Granular Polytetrafluoroethylene Resin from India: 2021–2023," dated concurrently with this notice (Issues and Decision Memorandum).

⁵ See *Granular Polytetrafluoroethylene Resin from India and the Russian Federation: Antidumping Duty Orders*, 87 FR 14514 (March 15, 2022) (*Order*).

⁶ See Issues and Decision Memorandum at Comment 2.

Notification to Importers Regarding the Reimbursement of Duties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during 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 Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under 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 or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: October 4, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the 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. Changes Since the Preliminary Results
- V. Discussion of the Issues
 - Comment 1: Calculation of Certain U.S. Movements Expenses
 - Comment 2: Correction of Clerical Errors
- VI. Recommendation

[FR Doc. 2024–23501 Filed 10–9–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–857]

Oil Country Tubular Goods From India: Preliminary Results of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that oil country tubular goods (OCTG) from India were not sold by Surya Roshni Limited (Surya) in the United States at less than normal value (NV) during the period of review (POR) September 1, 2022, through August 31, 2023. We invite interested parties to comment on these preliminary results.

DATES: Applicable October 10, 2024.

FOR FURTHER INFORMATION CONTACT: Brian Warnes, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0028.

SUPPLEMENTARY INFORMATION:

Background

On September 10, 2014, Commerce published the antidumping duty order on OCTG from India.¹ On September 6, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the Order for the POR.² Pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b)(1), Commerce received a timely request to conduct an administrative review of the Order from Surya.³ On November 15, 2023, Commerce initiated an administrative review of the Order.⁴ This review covers the sole mandatory respondent, Surya.

¹ See *Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders; and Certain Oil Country Tubular Goods From the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value*, 79 FR 53691 (September 10, 2014) (Order).

² See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List*, 88 FR 60923 (September 6, 2023).

³ See Surya's Letter, "Request for Administrative Review of Antidumping Duty Order," dated September 28, 2023.

⁴ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 88 FR 78298 (November 15, 2023).

On May 20, 2024, we extended the deadline for these preliminary results until no later than September 27, 2024.⁵ On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.⁶ The deadline for these preliminary results is now October 4, 2024.

For a complete description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum.⁷ A list of topics discussed in the Preliminary Decision Memorandum is included in the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Order⁸

The merchandise subject to the Order is certain OCTG from India. For a full description of the scope, see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. Export prices have been calculated in accordance with section 771 of the Act and NV was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, see the Preliminary Decision Memorandum.

Preliminary Results of Review

Commerce preliminarily determines that the following estimated weighted-average dumping margin exists for the period September 1, 2022, through August 31, 2023:

⁵ See Memorandum, "Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review," dated March 21, 2024.

⁶ See Memorandum, "Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings," dated July 22, 2024.

⁷ See Memorandum, "Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order on Oil Country Tubular Goods from India; 2022–2023," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁸ See Order, 84 FR at 33919.

Producer and/or exporter	Weighted-average dumping margin (percent)
Surya Roshni Limited	0.00

Disclosure and Public Comment

Commerce intends to disclose the calculations used in our analysis to parties in this review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs to Commerce 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 five days after the date for filing case briefs.⁹ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; (2) a brief summary of the argument; and (3) a table of authorities.¹⁰ Case and rebuttal briefs should be filed using ACCESS¹¹ and must be served on interested parties.¹²

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.¹³ Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its

⁹ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹⁰ See 19 CFR 351.309(c)(2) and (d)(2).
¹¹ *Id.*; see also 19 CFR 351.303 (for general filing requirements).

¹² See 19 CFR 351.303(f).
¹³ We use the term “issue” here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

requirements pertaining to the service of documents in 19 CFR 351.303(f).¹⁴
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, filed electronically via ACCESS. 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. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce’s electronic records system, ACCESS, by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.

Assessment Rates

Upon completion of the 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.¹⁵ If the weighted-average dumping margin is not zero or *de minimis* (i.e., less than 0.5 percent), then Commerce will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for each importer’s examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). Where an importer-specific *ad valorem* assessment rate is zero or *de minimis* in the final results of the review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. If Surya’s weighted-average dumping margin is zero or *de minimis* in the final results of the review, we will instruct CBP not to assess duties on any of its entries in accordance with the *Final Modification for Reviews*, i.e., “{w}here the weighted-average margin of dumping for the exporter is determined to be zero or *de minimis*, no antidumping duties will be assessed.”¹⁶

In accordance with Commerce’s “automatic assessment” practice, for entries of subject merchandise during the POR produced by Surya for which the producer did not know its merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others

¹⁴ See *APO and Service Final Rule*.
¹⁵ See 19 CFR 351.212(b).
¹⁶ See *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification*, 77 FR 8101, 8102 (February 14, 2012) (*Final Modification for Reviews*).

rate (i.e., 5.79 percent)¹⁷ if there is no rate for the intermediate company (or companies) involved in the transaction.¹⁸
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 administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Surya will be equal to the weighted-average dumping margin established in the final results of this administrative review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, a prior review, or in the less-than-fair-value investigation (LTFV) but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 5.79 percent, the rate established in the LTFV investigation of this proceeding.¹⁹ These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of our analysis of

¹⁷ See *Order*, 79 FR at 53693.
¹⁸ See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).
¹⁹ See *Order*, 79 FR at 53693.

issues raised by the parties in the written comments, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These preliminary results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(2) and 351.221(b)(4).

Dated: October 4, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the *Order*
- IV. Discussion of the Methodology
- V. Currency Conversion
- VI. Recommendation

[FR Doc. 2024–23488 Filed 10–9–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–858]

Oil Country Tubular Goods From India: Preliminary Results of Countervailing Duty Administrative Review; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to a producer and exporter of oil country tubular goods (OCTG) from India. The period of review (POR) is January 1, 2022, through December 31, 2022. Interested parties are invited to comment on these preliminary results.

DATES: Applicable October 10, 2024.

FOR FURTHER INFORMATION CONTACT: Thomas Cloyd, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1246.

SUPPLEMENTARY INFORMATION:

Background

On September 10, 2024, Commerce published the countervailing duty (CVD) order on OCTG from India.¹ On November 15, 2023, Commerce published in the **Federal Register** a notice of initiation of an administrative review of the *Order*.² On May 31, 2024, Commerce extended the deadline for the preliminary results until September 27, 2024.³ On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.⁴ The deadline for these preliminary results is now October 4, 2024.

For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.⁵ A list of topics included in the Preliminary Decision Memorandum is included in the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The merchandise covered by this *Order* is OCTG from India. For a complete description of the scope of the

¹ See *Certain Oil Country Tubular Goods from India and the Republic of Turkey: Countervailing Duty Orders and Amended Affirmative Final Countervailing Duty Determination for India*, 79 FR 53688 (September 10, 2014) (*Order*).

² See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 88 FR 78298 (November 15, 2023).

³ See Memorandum, “Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review,” dated May 31, 2024.

⁴ See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated July 22, 2024.

⁵ See Memorandum, “Decision Memorandum for Preliminary Results of the Administrative Review of the Countervailing Duty Order on Oil Country Tubular Goods from India; 2022,” dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Order, see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this CVD 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, Commerce preliminarily determines that there is a subsidy, *i.e.*, a financial contribution by an “authority” that gives rise to a benefit to the recipient, and that the subsidy is specific.⁶ For a full description of the methodology underlying our preliminary conclusions, see the Preliminary Decision Memorandum.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following net countervailable subsidy rate for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate 2022 (percent <i>ad valorem</i>)
Surya Roshni Limited	2.31

Disclosure and Public Comment

Commerce intends to disclose its calculations and analysis performed in connection with this preliminary determination to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce 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 five days after the date of filing case briefs.⁷ Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.⁸ All briefs must be filed electronically using ACCESS. An electronically filed document must be

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 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

⁸ See 19 CFR 351.309(c)(2) and (d)(2).

received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.⁹ Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹⁰

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 within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of 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 of the hearing.

Assessment Rates

Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue 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 injection has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce also intends, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amount shown for the company listed above with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2), Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised by parties in their comments, within 120 days after the date of publication of these preliminary results.

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 351.221(b)(4).

Dated: October 4, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Period of Review
- IV. Scope of the Order
- V. Subsidies Valuation
- VI. Benchmarks and Discount Rates
- VII. Analysis of Programs
- VIII. Recommendation

[FR Doc. 2024–23487 Filed 10–9–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE318]

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold its first Recreational Initiative Working Group meeting in Tampa, FL.

DATES: The meeting will convene Tuesday, October 29, 2023, from 9 a.m. to 5 p.m. and Wednesday, October 30, 2024, from 9 a.m. to 4 p.m., EDT.

ADDRESSES: The meeting will take place at the Gulf Council Office. You may “listen in” by accessing the log-on information by visiting our website at www.gulfcouncil.org.

Council address: Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Dr. Carrie Simmons, Executive Director, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to provide Working Group members with an opportunity to share their views on reef fish stock status and management, provide perspectives on what management “success” would look like, and offer initial thoughts on approaches that they would like to see the Council consider. The meeting agenda is as follows:

Tuesday, October 29, 2024; 9 a.m.–5 p.m., EDT

The meeting will begin with Welcome and Recreational Initiative Background, Introductions, Set the Stage and Review Meeting Purpose, History of Past and Current Goals and Objectives for Recreational Fisheries Management.

The group will review past challenges and successes of recreational reef fish management.

Wednesday, October 30, 2024; 9 a.m.–4 p.m., EDT

The Working Group will work on developing a vision, goals and objectives for Recreational Reef Fish Management. The Group will engage in a facilitated discussion and the meeting will end with closing remarks and logistics.

⁹ We use the term “issue” here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹⁰ See APO and Service Final Rule.

The full agenda and additional information will be posted on <https://gulfcouncil.org/recreational-initiative/>.

This meeting is being held in-person at the Gulf Council office, Tampa, FL. You may register for the webinar to listen-in only by visiting www.gulfcouncil.org and click on the meeting on the calendar.

The timing and order in which agenda items are addressed may change as required to effectively address the issue, and the latest version along with other meeting materials will be posted on the website as they become available.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid or accommodations should be directed to Kathy Pereira, (813) 348-1630, at least 15 days prior to the meeting date.

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

Dated: October 7, 2024.

Key Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-23463 Filed 10-9-24; 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; Atlantic Sea Scallop Fishery Management Plan Data Collection

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 December 9, 2024.

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 0648-0491 in the subject line of your comments. All comments received are part of the public record and will generally be posted on <https://www.regulations.gov> without change. 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 Colette Tweeddale, Fishery Management Specialist, Greater Atlantic Regional Fisheries Office, 55 Great Republic Dr., Gloucester, MA 01930, (978)-281-9335, colette.tweeddale@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for a renewal of an approved information collection.

Under the Magnuson-Stevens Fishery Conservation and Management Act, the Secretary of Commerce has the responsibility for the conservation and management of marine fishery resources. Much of this responsibility has been delegated to NOAA's National Marine Fisheries Service (NMFS). NMFS manages the Atlantic sea scallop (scallop) fishery through a set of regulations that limit catch of scallops and fishing vessel activity. In addition, regulations limit catch of certain other species of fish in order to minimize bycatch and bycatch mortality (bycatch is the catch and discard of species that are not targeted in the scallop fishery). Finally, the regulations control vessel permitting and the exchange of effort and quota allocations between vessels. In order to effectively manage these resources, track fishing effort and catch, and to allow vessel owners to exchange fishing trips and quota, NMFS must collect information through the reporting requirements included in this renewal. This renewal contains the following information collections: Vessel Monitoring System (VMS) requirements; Access area trip exchange application procedures; Individual Fishing Quota (IFQ) transfers; Cost recovery; and IFQ sector program.

Access Area Trip Exchange Application

The one-for-one access area trip exchange program provides flexibility to scallop vessels about where they may fish. Participants need to send an access area trip exchange application to NMFS with the following information: Vessel

name and permit number, owner name and signature, specification of the areas involved in the exchange. Both vessels involved in the exchange are required to submit forms for cross verification. This measure provides flexibility to vessels regarding which areas to fish, thereby reducing the possibility of revenue loss to those vessels that are unable to access some distant areas due to vessel capacity constraints.

IFQ Transfers

IFQ permit holders can temporarily and/or permanently transfer individual fishing quota from one IFQ vessel to another. Quota transfers are requested through the submission of transfer applications. Required information includes vessel information, quota transfer information, and authorizing signatures from both parties. The IFQ transfer program is entirely optional, and provides greater flexibility for IFQ permit holders by enabling them to increase their vessel's IFQ or for individuals to lease or sell IFQ if they choose not to fish the allocation.

Cost Recovery

Section 304(d)(2) of the Magnuson-Stevens Act (MSA) requires an IFQ cost recovery plan to recover management and enforcement costs for IFQ fisheries. The FMP includes an IFQ cost recovery program, whereby NMFS will collect up to 3% of ex-vessel value of landed product to cover actual costs directly related to enforcement and management of the IFQ program. IFQ permit holders are required to submit a cost recovery payment annually via a pre-existing Federal payment system called www.pay.gov, which is also currently used by the Alaska Region and the Southeast Region. Information submitted via the internet would require the user to establish an online account, including personal and financial information. This requirement is necessary in order to comply with the provisions of the MSA and to collect payments from individuals that have been granted an allocation to a public resource.

IFQ Sector Program

The FMP contains provisions that authorize allocation of a portion of the overall IFQ fishery total allowable catch (TAC) to a self-selected group of IFQ permit holders (sector), provided the sector provides adequate information describing the formation of the sector and its intended plan of operations. Individuals or other entities (corporations, cooperatives, etc.) proposing a sector are required to submit a Sector Allocation Proposal and

Operations Plan. Any person may submit a Sector Allocation Proposal for a group of limited access general category scallop vessels to the Council, at least 1 year in advance of the start of a sector, and request that the Sector be implemented through a framework procedure specified at § 648.55. A group that wants to form a Sector and receive an allocation is required to submit a legally binding Operations Plan to the Council and the Regional Administrator. The operations plan must be agreed upon and signed by all members of the sector and, if approved, would constitute a contract. This information is necessary to describe the proposed sector and the proposed rules under which the sector would operate. This information is used to determine whether this sector would maintain consistency with the goals and objectives of the FMP.

II. Method of Collection

Participants will submit paper applications by mail, facsimile, or email.

III. Data

OMB Control Number: 0648–0491.
Form Number(s): None.

Type of Review: Regular submission [extension of a current information collection].

Affected Public: Businesses and other for-profit organizations are primarily affected.

Estimated Number of Respondents: 647.

Estimated Time per Response: Cost recovery, 2 hours; Sector proposals, 150 hours; Sector operations plans, 100 hours; IFQ transfer application 35 hours; Access area trip exchange, 45 hours.

Estimated Total Annual Burden Hours: 980.

Estimated Total Annual Cost to Public: \$23,932.

Respondent's Obligation: Required to Obtain or Retain Benefits.

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 information collection request. 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,

Departmental PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–23437 Filed 10–9–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE371]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public hybrid meeting of its Groundfish Recreational and Advisory Panels to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). This meeting will be held in-person with a webinar option. Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Monday, October 28, 2024, at 12:30 p.m.

ADDRESSES: This meeting will be held at the Hilton Garden Inn, 100 High Street, Portsmouth, NH 03801; telephone: (603) 431–1499.

Webinar registration URL information: <https://nefmc-org.zoom.us/>

meeting/register/tJYkd-GgpjsGtx9oyjDbrnhazzPqUCH59WZ.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Cate O'Keefe, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Groundfish Recreational and Advisory Panels will meet to receive an update on development of draft alternatives in Framework Adjustment 69/Specifications and Management Measures, including potential recommendations to the Groundfish Committee. They will receive an update on development of the Atlantic Cod Management Transition Plan. The Panel's will also make recommendations to the Groundfish Committee, as appropriate. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O'Keefe, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: October 7, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–23468 Filed 10–9–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID 0648-XE372]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public hybrid meeting of its Groundfish Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). This meeting will be held in-person with a webinar option.

Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Tuesday, October 29, 2024, at 9 a.m.

ADDRESSES:

Meeting address: This meeting will be held at the Hilton Garden Inn, 100 High Street, Portsmouth, NH 03801; telephone: (603) 431-1499.

Webinar registration URL information: https://nefmc-org.zoom.us/j/9tj0rf-CtrT4jHdQAS16yNI82_YZ9x8joBKlT.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Cate O'Keefe, Executive Director, New England Fishery Management Council; telephone: (978) 465-0492.

SUPPLEMENTARY INFORMATION:**Agenda**

The Groundfish Committee will meet to discuss recommendations from the Recreational Advisory Panel, Groundfish Advisory Panel, and Groundfish Plan Development Team. They will receive an update on development of draft alternatives in Framework Adjustment 69/ Specifications and Management Measures, including potential recommendations to the Council. The Committee will receive an update on development of the Atlantic Cod Management Transition Plan. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues

specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O'Keefe, Executive Director, at (978) 465-0492, at least 5 days prior to the meeting date.

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

Dated: October 7, 2024.

Key Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-23467 Filed 10-9-24; 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; Nomination Process for National Marine Sanctuaries**

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 April 30, 2024 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: Nomination Process for National Marine Sanctuaries.

OMB Control Number: 0648-0682.

Form Number(s): None.

Type of Request: Regular submission, revision and extension of a current information collection.

Number of Respondents: 7.

Average Hours per Response: 115 hours per nomination; 8 hours for additional information.

Total Annual Burden Hours: 591.

Needs and Uses: This request is for a revision and extension of an existing information collection necessary to provide the American public an opportunity to nominate marine areas which the National Oceanic and Atmospheric Administration (NOAA) may consider for designation as a national marine sanctuary, under the National Marine Sanctuaries Act (NMSA). The revision adds a Request for Additional Information to accurately reflect the burden imposed by requesting follow-up information.

National marine sanctuary regulations provide that the public can submit areas of the marine and Great Lakes environments for consideration by NOAA as a national marine sanctuary through the sanctuary nomination process (15 CFR 922.12). Persons wanting to submit nominations for consideration should submit information on the qualifying criteria and management considerations for the site to be nominated. The Office of National Marine Sanctuaries reviews the submissions, which could result in the nomination being added to an inventory of areas that NOAA may consider for sanctuary designation at some point in the future. Sanctuary designation is a separate public process that would be conducted pursuant to the requirements of the National Marine Sanctuaries Act, and all other applicable laws. This proposed information collection is for national marine sanctuary nominations received pursuant to NOAA regulations that provide that the public may nominate special places of the marine environment through the sanctuary nomination process at 15 CFR 922.12.

Affected Public: Individuals, non-profit institutions; Federal, State, local, government, Native Hawaiian organizations; business or other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

Legal Authority: 16 U.S.C. 1431 *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 0648–0682.

Sheleen Dumas,

Departmental PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–23436 Filed 10–9–24; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE367]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico

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

ACTION: Notice; issuance of letter of authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, its implementing regulations, and NMFS’ MMPA Regulations for Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico (GOM), notification is hereby given that NMFS has issued a Letter of Authorization (LOA) to WesternGeco for the take of marine mammals incidental to geophysical survey activity in the GOM.

DATES: This LOA is effective from October 3, 2024 through November 15, 2024.

ADDRESSES: The LOA, LOA request, and supporting documentation are available online at: <https://www.fisheries.noaa.gov/marine-mammal-protection/issued-letters-authorization-oil-and-gas-industry-geophysical-survey>. In case of problems accessing these documents, please call the contact listed below (**FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Rachel Wachtendonk, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce 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 issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined “negligible impact” in 50 CFR 216.103 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.

Except with respect to certain activities not pertinent here, 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).

On January 19, 2021, we issued a final rule with regulations to govern the unintentional taking of marine mammals incidental to geophysical survey activities conducted by oil and gas industry operators, and those persons authorized to conduct activities on their behalf (collectively “industry operators”), in U.S. waters of the GOM over the course of 5 years (86 FR 5322). The rule was based on our findings that the total taking from the specified activities over the 5-year period will have a negligible impact on the affected species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of those species or stocks for subsistence uses, and became effective on April 19, 2021.

The regulations at 50 CFR 217.180 *et seq.* allow for the issuance of LOAs to industry operators for the incidental take of marine mammals during geophysical survey activities and prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat (often referred to as mitigation), as well as requirements pertaining to the monitoring and reporting of such taking. Under § 217.186 (e), issuance of an LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations and a determination that the amount of take authorized under the LOA is of no more than small numbers.

NMFS subsequently discovered that the 2021 rule was based on erroneous take estimates. We conducted another rulemaking using correct take estimates and other newly available and pertinent information relevant to the analyses supporting some of the findings in the 2021 final rule and the taking allowable under the regulations. We issued a final rule in April 2024, effective May 24, 2024 (89 FR 31488).

The 2024 final rule made no changes to the specified activities or the specified geographical region in which those activities would be conducted, nor to the original 5-year period of effectiveness. In consideration of the new information, the 2024 rule presented new analyses supporting affirmance of the negligible impact determinations for all species, and affirmed that the existing regulations, which contain mitigation, monitoring, and reporting requirements, are consistent with the “least practicable adverse impact” standard of the MMPA.

Summary of Request and Analysis

NMFS issued a LOA to TGS on September 27, 2023, for the take of marine mammals incidental to a 3-dimensional ocean bottom node survey in the Green Canyon, Ewing Bank, and Atwater Valley protraction areas, including approximately 380 lease blocks, effective September 27, 2023, through September 28, 2024. Please see the **Federal Register** notification (88 FR 68106, October 3, 2023) for additional detail regarding the LOA and the planned survey activity.

On December 20, 2023, TGS requested the transfer of the LOA to WesternGeco, its partner in the planned survey effort. WesternGeco confirmed to NMFS that it similarly requested transfer of the LOA. No other changes were requested. The revised LOA remained effective through

September 28, 2024. Please see the **Federal Register** notice of issuance of a revised LOA (89 FR 5864, January 30, 2024) for additional detail regarding the transfer.

WesternGeco notified NMFS that due to survey delays it had not completed the survey plan described in the initial LOA request submitted by TGS and, because the original LOA has expired, has requested that an additional LOA be issued effective through November 15, 2024, to cover completion of the planned survey effort.

Although this is technically a new LOA, NMFS considers this to be functionally an extension of the original LOA, as the survey activity considered herein represents the conclusion of the originally planned survey. Of the originally planned 65 days of sound source operations, approximately 16 days of surveying remains, all in Zone 5. There are no other changes to WesternGeco's planned activity, as described in the original notice of issuance (88 FR 68106, October 3, 2023). On this basis, NMFS has updated take estimates based on information provided in the 2024 final rule (89 FR 31488, April 24, 2024), and corresponding with the estimated 16 days of remaining survey activity. As WesternGeco's is using conventional airgun sources consisting of 28 elements, with a total volume of 5,240 cubic inches (or the less-impactful

Gemini source), we have used the 5,110 cu in airgun array proxy to estimate the take numbers.

Based on the results of our analysis, NMFS has determined that the level of taking expected for this survey and authorized through the LOA is consistent with the findings made for the total taking allowable under the regulations. See table 1 in this notice and table 6 of the rule (89 FR 31488, April 24, 2024).

Small Numbers Determination

Under the GOM rule, NMFS may not authorize incidental take of marine mammals in an LOA if it will exceed "small numbers." In short, when an acceptable estimate of the individual marine mammals taken is available, if the estimated number of individual animals taken is up to, but not greater than, one-third of the best available abundance estimate, NMFS will determine that the numbers of marine mammals taken of a species or stock are small (89 FR 31535, May 24, 2024). For more information please see NMFS' discussion of small numbers in the 2021 final rule (86 FR 5438, January 19, 2021).

The take numbers for authorization are determined as described above in the Summary of Request and Analysis section. Subsequently, the total incidents of harassment for each species are multiplied by scalar ratios to produce a derived product that better

reflects the number of individuals likely to be taken within a survey (as compared to the total number of instances of take), accounting for the likelihood that some individual marine mammals may be taken on more than 1 day (86 FR 5404, January 19, 2021; 89 FR 31535, May 24, 2024). The output of this scaling, where appropriate, is incorporated into adjusted total take estimates that are the basis for NMFS' small numbers determinations, as depicted in table 1. Normally, a survey with a duration of 16 days would not apply scalar ratios for the small numbers determination. However, scalar ratios were used in this instance since we consider this survey a continuation of the original 65 day survey.

This product is used by NMFS in making the necessary small numbers determinations through comparison with the best available abundance estimates (see discussion at 86 FR 5391, January 19, 2021). For this comparison, NMFS' approach is to use the maximum theoretical population, determined through review of current stock assessment reports (SAR; <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>) and model-predicted abundance information (<https://seamap.env.duke.edu/models/Duke/GOM/>). Information supporting the small numbers determinations is provided in table 1.

TABLE 1—TAKE ANALYSIS ¹

Species	Authorized take	Scaled take	Abundance ²	Percent abundance
Rice's whale	0	n/a	51	n/a
Sperm whale	112	47.4	3,007	1.6
<i>Kogia</i> spp	³ 48	14.7	980	1.7
Beaked whales	489	49.4	803	6.1
Rough-toothed dolphin	372	106.9	4,853	2.2
Bottlenose dolphin	296	85.0	165,125	0.1
Clymene dolphin	208	59.6	4,619	1.3
Atlantic spotted dolphin	108	31.0	21,506	0.1
Pantropical spotted dolphin	2,834	813.4	67,225	1.2
Spinner dolphin	⁴ 152	14.4	5,548	0.3
Striped dolphin	525	150.6	5,634	2.7
Fraser's dolphin	137	39.2	1,665	2.4
Risso's dolphin	87	25.6	1,974	1.3
Blackfish ⁵	804	237.3	6,113	3.9
Short-finned pilot whale	113	33.3	2,741	1.2

¹ Scalar ratios were applied to "Authorized Take" values as described at 86 FR 5322, 5404 (January 19, 2021) to derive scaled take numbers shown here.

² Best abundance estimate. For most taxa, the best abundance estimate for purposes of comparison with take estimates is considered here to be the model-predicted abundance (Garrison *et al.*, 2023). For Rice's whale, Atlantic spotted dolphin, and Risso's dolphin, the larger estimated SAR abundance estimate is used.

³ Includes 2 takes by Level A harassment and 46 takes by Level B harassment. Small numbers determination made on basis of scaled Level B harassment take plus authorized Level A harassment take.

⁴ Modeled take of 50 increased to account for potential encounter with a group of average size (Maze-Foley and Mullin, 2006).

⁵ The "blackfish" guild includes melon-headed whales, false killer whales, pygmy killer whales, and killer whales.

Based on the analysis contained herein of WesternGeco's modified

survey activity described in its LOA modification request and the

anticipated take of marine mammals, NMFS finds that small numbers of

marine mammals will be taken relative to the affected species or stock sizes (*i.e.*, less than one-third of the best available abundance estimate) and therefore the taking is of no more than small numbers.

Authorization

NMFS has determined that the level of taking for this modified LOA request is consistent with the findings made for the total taking allowable under the incidental take regulations and that the amount of take authorized under the LOA is of no more than small numbers. Accordingly, we have issued an LOA to WesternGeco authorizing the take of marine mammals incidental to its geophysical survey activity, as described above.

Dated: October 7, 2024.

Kimberly Damon-Randall,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2024-23483 Filed 10-9-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE306]

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of its Citizen Science Operations Committee October 30–31, 2024. The meeting will be held in Charleston, SC.

DATES: The Citizen Science Operations Committee meeting will be held Wednesday, October 30, 2024, from 1 p.m. until 5 p.m. and Thursday, October 31, 2024, from 8:30 a.m. until 12 p.m.

ADDRESSES: The meeting will be held at the South Atlantic Fishery Management Council office, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405. The meeting is open to the public and will also be available via webinar. Webinar registration, an online public comment form, and briefing book materials will be available two weeks prior to the meeting at: <https://safmc.net/advisory-panel-meetings/>. There will be an opportunity for public comment at the beginning of the meeting.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julia Byrd, Citizen Science Program Manager, SAFMC; phone: (843) 302-8439 or toll free: (866) SAFMC-10; fax: (843) 769-4520; email: julia.byrd@safmc.net.

SUPPLEMENTARY INFORMATION: The Citizen Science Operations Committee serves as advisors to the Council's Citizen Science Program. Committee members include representatives from the Council's Citizen Science Advisory Panel Pool, NOAA Fisheries' Southeast Regional Office, NOAA Fisheries' Southeast Fisheries Science Center, and the Council's Science and Statistical Committee. Their responsibilities include developing programmatic recommendations, reviewing policies, providing program direction/multi-partner support, identifying citizen science research needs, and providing general advice.

Agenda items include: the Citizen Science Program's initial evaluation plan, including researchers presenting their findings to help establish baseline levels of knowledge about, confidence in, and trust in the citizen science process of collecting data to inform fisheries management, committee discussion, and development of programmatic recommendations; a Citizen Science Program and Project update; and other business.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: October 7, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-23461 Filed 10-9-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE307]

Fisheries of the U.S. Caribbean; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 84 Assessment Webinar IX for U.S. Caribbean Yellowtail Snapper and Stoplight Parrotfish.

SUMMARY: The SEDAR 84 assessment process of U.S. Caribbean yellowtail snapper and stoplight parrotfish will consist of a Data Workshop, and a series of assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 84 assessment webinar IX will be held Wednesday, October 30, 2024, from 1 p.m. to 4 p.m., Eastern Time.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; phone: (843) 571-4366; email: julie.neer@safmc.net.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop, (2) a series of assessment webinars, and (3) A Review Workshop. The product of the Data Workshop is a report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The assessment webinars produce a report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The product of the Review Workshop is an Assessment Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office,

HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion during the Assessment webinar IX are as follows:

Panelists will review and discuss and finalize the assessment modeling for stoplight parrotfish and yellowtail snapper.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 6 U.S.C. 1801 *et seq.*

Dated: October 7, 2024.

Key Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-23466 Filed 10-9-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC24-17-000]

Commission Information Collection Activities (FERC-725L) Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Energy Regulatory Commission

(Commission or FERC) is soliciting public comment on the currently approved information collection, FERC 725L (Mandatory Reliability Standards for the Bulk-Power System: MOD Reliability Standards). The 60-day notice comment period ended on September 27, 2024, and no comments were received.

DATES: Comments on the collection of information are due November 12, 2024.

ADDRESSES: Send written comments on FERC-725L to OMB through www.reginfo.gov/public/do/PRAMain. Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Number (1902-0261) in the subject line of your comments. Comments should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain.

Please submit copies of your comments to the Commission. You may submit copies of your comments (identified by Docket No. IC24-17-000) by one of the following methods:

Electronic filing through <https://www.ferc.gov>, is preferred.

- **Electronic Filing:** Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.

- For those unable to file electronically, comments may be filed by USPS mail or by other delivery methods:

- **Mail via U.S. Postal Service Only:** Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

- **All other delivery methods:** Federal Energy Regulatory Commission, Secretary of the Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: OMB submissions must be formatted and filed in accordance with submission guidelines at www.reginfo.gov/public/do/PRAMain. Using the search function under the "Currently Under Review" field, select Federal Energy Regulatory Commission; click "submit," and select "comment" to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: <https://www.ferc.gov/ferc-online/overview>. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at: (866) 208-3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <https://www.ferc.gov/ferc-online/overview>.

FOR FURTHER INFORMATION CONTACT: Kayla Williams may be reached by

email at DataClearance@FERC.gov, telephone at (202) 502-6468.

SUPPLEMENTARY INFORMATION:

Title: FERC-725L, Mandatory Reliability Standards for the Bulk-Power System: MOD Reliability Standards.

OMB Control No.: 1902-0261.

Type of Request: Three-year extension of the FERC-725L information collection requirements with no changes to the reporting requirements.

Abstract: MOD Reliability Standards ensure that generators remain in operation during specified voltage and frequency excursions, properly coordinate protective relays and generator voltage regulator controls, and ensure that generator models accurately reflect the generator's capabilities and equipment performance.

On May 30, 2013, the North American Electric Reliability Corporation (NERC) filed a petition explaining that the reliability of the Bulk-Power System benefits from "good quality simulation models of power system equipment," and that "model validation ensures the proper performance of the control systems and validates the computer models used for stability analysis." NERC further stated that the Reliability Standards will enhance reliability because the tests performed to obtain model data may reveal latent defects that could cause "inappropriate unit response during system disturbances."¹ Subsequently, on March 20, 2014, the Commission approved Reliability Standards MOD-025-2, MOD-026-1, and MOD-027-1. These Standards were intended to address generator verifications needed to support Bulk-Power System reliability that would also ensure that accurate data is verified and made available for planning simulations.¹

On May 1, 2014,² the Commission approved Reliability Standards MOD-032-1 and MOD-033-2. These Standards were to address "system-level modeling data and validation requirements necessary for developing planning models and the Interconnection-wide cases that are integral to analyzing the reliability of the Bulk-Power System."

MOD-025-2, MOD-026-1, MOD-027-1, MOD-031-3, MOD-032-1, and MOD-033-2 are all currently approved within the FERC-725L information collection. The reporting requirements associated with each standard will not change as a result of this extension request.

¹ Final Rule in Docket No. RM13-16-000.

² NERC Petition for Approval of Five Proposed Reliability Standards MOD-025-2, MOD-026-1, MOD-027-1, PRC-019-1, and PRC-024-1 submitted to FERC on 5/30/2013.

Type of Respondents: NERC-registered entities including generator owners, transmission planners, planning authorities, balancing

authorities, resource planners, transmission service providers, reliability coordinators, and transmission operators.³

*Estimate of Annual Burden:*⁴ The Commission estimates the annual public reporting burden⁵ and cost for the information collection as:

MOD-025-2

[Verification and data reporting of generator real and reactive power capability and synchronous condenser reactive power capability]

	Number of respondents ⁶	Annual number of responses per respondent	Total number of responses	Average burden & cost per response	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Verification and Data Reporting (Attachment 2).	1210 (GO)	1	1210	⁷ 6 hrs.; \$463.74	7,260 hrs.; \$561,125.40.	\$463.74
Evidence Retention	1210 (GO)	1	1210	⁸ 1 hr.; \$39.58	1210 hrs.; \$47,891.80.	39.58
Total					8,470 hrs.; \$609,017.20.	

MOD-026-1

[Verification of models and data for generator excitation control system or plant volt/variance control functions]

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Instructions for obtaining excitation control system or plant voltage/variance control function model.	203 (TP)	1	203	8 hrs.; \$618.32	1,624 hrs.; \$125,518.96.	\$618.32
Documentation on generator verification.	605 (GO)	1	605	8 hrs.; \$618.32	4,840 hrs.; \$374,083.60.	618.32
Evidence Retention	808 (GO and TOP).	1	808	1 hr.; \$39.58	808 hrs.; \$31,948.32.	39.58
Total					7,272 hrs.; \$531,550.88.	

MOD-027-1

[Verification of models and data for turbine/governor and load control or active power/frequency control functions]

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Instructions for obtaining excitation control system or plant voltage/variance control function model.	203 (TP)	1	203	8 hrs.; \$618.32	1,624 hrs.; \$125,518.96.	\$618.32
Documentation on generator verification.	605 (GO) ⁹	1	605	8 hrs.; \$618.32	4,840 hrs.; \$374,083.60.	618.32
Evidence Retention	808 (GO and TP).	1	808	1 hr.; \$39.58	808 hrs.; \$31,980.64.	39.58

³ In subsequent portions of this notice, the following acronyms will be used:

PA = Planning Authority, GO = Generator Owner, TP = Transmission Planner, BA = Balancing Authority, RP = Resource Planner, TSP = Transmission Service Provider, RC = Reliability Coordinator, TOP = Transmission Operator.

⁴ "Burden" is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. For further explanation of what is included in the information collection burden, reference 5 CFR 1320.3.

⁵ Each of the five MOD standards in the FERC-725L information collection previously contained "one-time" components to their respondent burden.

These one-time burden categories consisted primarily of activities related to establishing industry practices and developing data validation procedures tailored toward these reliability standards and their reporting requirements. None of the one-time burdens apply any longer, so they are being removed from the FERC-725L information collection.

MOD-027-1—Continued

[Verification of models and data for turbine/governor and load control or active power/frequency control functions]

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Total					7,272 hrs.; \$531,583.20.	

MOD-031-3 (DEMAND AND ENERGY DATA), INCLUDED IN FERC-725L

Reliability standard MOD-031-3	Number and type of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ¹⁰	Total annual burden hours & total annual cost	Cost per respondent
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Develop summary in accordance with Requirement R1, Subparts 1.5.4 and 1.5.5.	607 (DP, TP and/or BA).	1	607	8 hrs.; \$618.32	4,856 hrs.; \$375,320.24.	\$618.32
New Total for MOD-031-3 for Renewal.					4,856 hrs.; \$375,320.24.	

MOD-032-1

[Verification of models and data for turbine/governor and load control or active power/frequency control functions]

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Data Submittal	2,126 (BA, GO, PA/PC, RP, TO, TP, and TSP).	1	2,126	8 hrs.; \$618.32	17,008 hrs.; \$1,314,548.32.	\$618.32
Evidence Retention	2,126 (BA, GO, PA/PC, RP, TO, TP, and TSP).	1	2,126	1 hr.; \$39.58	2,126 hrs.; \$84,147.08.	39.58
Total					19,134 hrs.; \$1,398,695.40.	

MOD-033-2 (FORMERLY MOD-033-1)

[Steady-state and dynamics system model validation]

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Data Submittal	177 (RC and TOP).	1	177	8 hrs.; \$618.32	1,416 hrs.; \$109,442.64.	\$618.32
Evidence Retention	239 (PA/PC, RC, and TOP).	1	239	1 hr.; \$39.58	239 hrs.; \$9,459.62	39.58
New Total for MOD-033-2 Renewal.					1,655 hrs.; \$118,902.26.	

The total annual estimated burden and cost for the FERC-725L information collection is 48,659 hours and \$2,255,507.94 respectively.

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: October 2, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-23297 Filed 10-9-24; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2023-0445; FRL-11370-05-OCSPP]

Pesticides; Framework for Interagency Collaboration To Review Potential Antibacterial and Antifungal Resistance Risks Associated With Pesticide Use; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is announcing the availability of the final framework for expanding interagency collaboration to improve the communication and

knowledge base within the federal family to fully consider potential adverse impact of pesticides on efficacy of human and animal drugs. In particular, the use of antifungal and antibacterial pesticides that can potentially lead to resistance in human and animal pathogens and may compromise the effectiveness of medically important antibacterial and antifungal drugs.

DATES: The Framework is effective October 10, 2024.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2023-0445, is available online at <https://www.regulations.gov>. Additional instructions for visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Jennings, Immediate Office (7501M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (706) 355-8574; email address: jennings.susan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general, although this action may be of particular interest to those persons who may be interested in assessments of potential risks to human and animal health where the use of certain pesticides could potentially result in antimicrobial resistance that compromises the effectiveness of medically important antibacterial and antifungal drugs. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

This action is being taken under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*).

C. What action is the Agency taking?

EPA is announcing the availability of a final Framework that outlines a process for EPA's collaboration with other federal agencies that recognizes the benefits of these pesticides to agriculture while minimizing their

impact on public health and considers the goals of the One Health approach. While developing this Framework, EPA has coordinated with HHS and USDA, under the oversight of the White House Executive Office of the President. Each of these agencies is charged with protecting health in areas that are directly impacted by resistance resulting from pesticides or drug products used to protect humans, animals, or plants. This Framework clarifies that EPA intends to establish a process with those other federal agencies to consider their input when EPA evaluates antibacterial and antifungal pesticide products that may adversely impact the efficacy of human or animal drugs.

EPA is issuing this Framework to provide information and clarification to pesticide applicants, growers, the public health community, and the public about EPA's process for considering resistance issues related to regulatory decisions on antibacterial and antifungal pesticides with other federal agencies. While the requirements in FIFRA and the EPA regulations are binding on EPA and applicants, this Framework is not binding on EPA personnel, pesticide registrants and applicants, or the public. EPA may depart from the Framework where circumstances warrant and without prior notice. Likewise, pesticide applicants may assert that the Framework is not applicable to a specific pesticide or decision. Registrants and applicants may also propose alternative processes to the final Framework in any application to EPA.

D. Why is the Agency taking this action?

Antimicrobial resistance in bacteria and fungi is a top threat to the public's health and a priority across the globe. The Centers for Disease Control and Prevention report that there are nearly 3 million antimicrobial-resistant infections and more than 35,000 associated deaths in the U.S. each year. According to USDA, plant diseases are also persistent threats to agricultural crops and global food security, having a significant impact on yields and quality. These diseases result in billions of dollars in economic losses and management inputs each year to crops, landscapes, and forests in the U.S. Plant diseases reduce yields, lower product quality or shelf-life, decrease aesthetic or nutritional value, and may contaminate food and feed with toxic compounds.

Determining a compound's potential to result in the development of antimicrobial resistance is complex. This Framework is intended to expand interagency collaboration to improve the

⁶ The number of respondents for MOD-025-2/ MOD-026-1/ MOD-027-1/ MOD-31-3/ MOD-032-1/ MOD-033-2 are from the NERC compliance registry April 16, 2024.

⁷ The estimated hourly cost (salary plus benefits) based on the Bureau of Labor Statistics (BLS), as of 2023, for an Electrical Engineer (17-2071) \$77.29/hr.

⁸ The estimated hourly cost (salary plus benefits) based on the Bureau of Labor Statistics (BLS), as of 2023 Information and Record Clerk (43-4199) \$39.58/hr.

⁹ It is estimated that the applicable numbers of generator owner respondents used to calculate the public reporting burden for these standards MOD-026-1, MOD-027-1, MOD-031-3, MOD-032-1, and MOD-033-1 is half of total numbers of GO (605=1210/2) due to the higher applicability threshold for those Reliability Standards.

¹⁰ The estimated hourly cost (salary plus benefits) based on the Bureau of Labor Statistics (BLS), as of 2023, for an Electrical Engineer (17-2071) \$77.29/hr.

communication and knowledge base within the federal family to fully consider potential adverse impact of pesticides on efficacy of human and animal antibacterial and antifungal drugs.

II. Background

On September 26, 2023, EPA and the other federal agencies issued a document entitled “Concept Note: Soliciting Feedback from Stakeholders on the Structure of a Proposed Framework to Assess the Risk to the Effectiveness of Human and Animal Drugs Posed by Certain Antibacterial or Antifungal Pesticides” (88 FR 65998) (FRL–11370–01–OCSPP). The concept note was intended to be the first step in creating a process to improve assessments of potential risks to human and animal health where the use of certain pesticides could potentially result in antimicrobial resistance that compromises the effectiveness of medically important antibacterial and antifungal drugs. The concept note solicited stakeholder input on the proposed structure for the process and potential solutions, research, and mitigation approaches to reduce the spread of resistance. The concept note posed several questions about how resistance occurs and is spread. The Agency received many comments; however, very few directly responded to the specific charge questions asked by the concept paper. The agencies did not receive sufficient information to resolve the many scientific questions about assessing the potential risk of antifungal or antibacterial pesticides to adversely impact the efficacy of human or animal drugs.

On July 2, 2024, EPA announced the availability of and requested comment on the draft framework entitled “Pesticides; Final White Paper: Framework for Interagency Collaboration to Review Potential Antibacterial and Antifungal Resistance Risks Associated with Pesticide Use” (89 FR 54819) (FRL–11370–03–OCSPP). Fourteen comments were received. Commenters included grower groups (three), industry groups (four), consulting groups (one), public interest groups (one), human health groups (three), animal health group (one), and one private citizen.

These groups raised a number of issues. The industry and grower groups stressed the benefits of pesticides, the need for a transparent process, concerns about the research uncertainties, and several advocated for EPA to wait to take action until the scientific issues are more resolved. The health groups were concerned about the implications of

resistance to humans and animals who need effective drugs to combat disease.

All public comments and EPA’s responses to comments received, including those that do not raise significant issues or substantially change the proposed requirements, are included in Response to Comments document that is available in the docket for this action. After considering the public comments, EPA is issuing the Framework.

Authority: 7 U.S.C. 136 *et seq.*

Dated: September 26, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024–22947 Filed 10–9–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2023–0288; FRL–11108–02–OCSPP]

Pesticides; Interim Guidance for the Evaluation of Products for Claims Against Viruses; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is announcing the availability of interim guidance to expand the availability of virucidal claims for antimicrobial pesticides and provide a framework for registrants who seek to make such claims. This interim guidance reiterates recommended test methods and guidance for the addition of virucidal claims to products that meet the criteria for hard surface disinfection claims and the addition of virucidal claims to products that meet the criteria for food/non-food contact sanitizer claims consistent with current test guidelines. This guidance specifically covers the addition of a virucidal claim to a product that has met the criteria for a bactericidal disinfectant and/or sanitizer. Pursuant to this guidance, the Agency intends to grant the addition of virucidal claims associated with sanitizer claims for a time-limited period of a maximum of ten years. Prior to the end of the ten-year period, the Agency will review the record and may terminate the policy, make suggestions for changes to the policy, as necessary, or decide to make the policy permanent. The methods and performance standards applicable to this expanded availability of virucidal claims are the same test methods and performance standards that are currently used to

support existing virucidal claims and thus there are no expectations of a reduction of product performance against viruses.

DATES: This interim guidance is effective October 10, 2024.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2023–0288, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Tahirah Morris, Antimicrobial Division (7510M), Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0798; email address: morris.tahirah@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the general public and may be of specific interest to persons or entities that register antimicrobial pesticides. Since a potentially broad range of entities may be interested in this action, the Agency has not attempted to describe all the specific entities that may be interested. If you have any questions regarding the applicability of this interim guidance to a particular entity or registration action, contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency’s authority for taking this action?

EPA is issuing this guidance pursuant to its authority under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*

C. What action is the Agency taking?

EPA is announcing the availability of interim guidance to expand the availability of virucidal claims for antimicrobial pesticides and provide a framework for registrants who seek to make such claims. The guidance document was revised based on the public comments received in 2023 (88 FR 45418, July 17, 2023 (FRL–11108–01–OCSPP)). EPA received 5 comments, which are summarized and responded to in a response to comment document that is available in the docket.

This interim guidance reiterates recommended test methods and guidance for the addition of virucidal claims to products that meet the criteria for hard surface disinfection claims and

the addition of virucidal claims to products that meet the criteria for food/non-food contact sanitizer claims consistent with current test guidelines. This guidance specifically covers the addition of a virucidal claim to a product that has met the criteria for a bactericidal disinfectant and/or sanitizer.

Pursuant to this guidance, the Agency intends to grant the addition of virucidal claims associated with sanitizer claims for a time-limited period of a maximum of ten years. Prior to the end of the ten-year period, the Agency will review the record and may terminate the policy, make suggestions for changes to the policy, as necessary, or decide to make the policy permanent. The methods and performance standards applicable to this expanded availability of virucidal claims are the same test methods and performance standards that are currently used to support existing virucidal claims and thus there are no expectations of a reduction of product performance against viruses.

II. Background

Historically, EPA has approved claims for efficacy against viruses only as additional claims on certain antimicrobial products, such as those with sterilant and disinfectant claims, but not those that bear only sanitizer claims.

This guidance is intended to allow registrants to provide consumers with additional products that are effective against viruses including SARS-CoV-2. This guidance reiterates recommended test methods and guidance for the addition of virucidal claims to products that meet the criteria for hard surface disinfection claims in OCSPP 810.2200, Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing.

Products with only sanitizer claims should meet the test guidance requirements as described in OCSPP 810.2300 Sanitizers for Use on Hard Surfaces—Efficacy Data Recommendations (food or non-food contact sanitization) to treat hard, non-porous surfaces before a virucidal claim is added pursuant to this guidance.

Since there will be no changes to the test methods or performance standards recommended for virus claims, there is no concern about a reduced level of efficacy against viruses. Products that meet the basic criteria to allow for sanitizer claims and have data to support the addition of virucidal label claims pursuant to this guidance, may be used in non-healthcare use-sites in residential, commercial, and institutional settings (e.g., cafeterias

specifically on hard, non-porous surfaces).

Additional anticipated benefits include the availability of more products with reduced contact times (time the surface must remain wet) and/or more products on EPA's Design for the Environment list that are also effective against viruses. The expansion of the availability of virucidal claims under this guidance will facilitate the addition of virus claims to products bearing only sanitizer claims.

III. Do guidance documents contain binding requirements?

As guidance, these documents are not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice. While EPA has made every effort to ensure the accuracy of the discussion in the guidance, the obligations of EPA and the regulated community are determined by statutes, regulations, or other legally binding documents. In the event of a conflict between the discussion in the guidance documents and any statute, regulation, or other legally binding document, the guidance documents will not be controlling.

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 4, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024–23471 Filed 10–9–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2023–0580; FRL–12332–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Publicly Owned Treatment Works (POTW) Influent Per- and Polyfluoroalkyl Substances (PFAS) Study and National Sewage Sludge Survey (NSSS) (New)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Publicly Owned Treatment Works (POTW) Influent Per- and Polyfluoroalkyl Substances (PFAS) Study and National Sewage Sludge Survey (NSSS) (EPA ICR Number 2799.01, OMB Control Number 2040–

NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request for approval of a new collection. Public comments were previously requested via the **Federal Register** on March 26, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before November 12, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OW–2023–0580, to EPA online using www.regulations.gov (our preferred method), by email to OW-Docket@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Sean Dempsey, Engineering and Analysis Division, Office of Science and Technology, (4303T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–564–5088; email address: Dempsey.Sean@epa.gov.

SUPPLEMENTARY INFORMATION: This is a request for approval of a new collection. 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.

Public comments were previously requested via the **Federal Register** on March 26, 2024 during a 60-day comment period (89 FR 20962). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center,

WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: This data collection is intended to gather essential data to identify and quantify sources of per- and polyfluoroalkyl substances (PFAS) discharges, prioritize industrial categories for potential regulation, and establish a current national data set of sewage sludge characteristics. The data collection will support two separate EPA studies—the POTW Influent PFAS Study and the National Sewage Sludge Survey (NSSS).

The Clean Water Act directs the EPA to develop national regulations known as Effluent Limitations Guidelines and Standards (ELGs) to place limits on the pollutants that are discharged by categories of industry to surface waters and POTWs. Additionally, Section 405(d) of the Clean Water Act requires that the EPA establish requirements for the use or disposal of sewage sludge and review the regulations every two years to identify additional pollutants.

For many decades, industrial facilities have used and discharged PFAS into the environment. PFAS are a class of synthetic chemicals of concern to the EPA because of their widespread use and potential to accumulate in the environment. Certain PFAS are known to cause adverse ecological and human health effects.

The EPA will require, through an OMB-approved Information Collection Request, a subset of large POTWs across the United States to complete an electronic questionnaire and collect and analyze wastewater and sewage sludge samples. The data collection activities will produce a robust data set that will characterize the type and quantity of PFAS in wastewater discharges from industrial users (including industrial categories that the EPA has determined historically or currently use PFAS but for which there is insufficient PFAS monitoring data available), domestic wastewater or sewage, and POTW influent, effluent, and sewage sludge. The wastewater sampling data will primarily be used to identify and prioritize industrial point source categories where additional study or regulations may be warranted to control PFAS discharges. The sewage sludge sampling will fulfill the EPA's data needs for the upcoming NSSS by establishing a current national data set of sewage sludge characteristics which the EPA will subsequently use to inform upcoming risk assessments and the need for future regulations and guidance

pertaining to the management of sewage sludge.

As part of the POTW Influent PFAS Study and NSSS, the EPA estimates that approximately 400 POTWs (individual wastewater or standalone wastewater treatment plans, as defined by Section 212 of the Clean Water Act, which is owned by a state or municipality) with a daily design flow rates greater than or equal to 10 million gallons per day (MGD) and a service population greater than or equal to 50,000 people will be required to complete an electronic questionnaire. The questionnaire will gather POTW-specific information and data on industrial users discharging to the POTW, known or suspected sources of PFAS discharges to the POTW, and wastewater and sewage sludge management practices of the POTW. The EPA will use the information and data collected in the questionnaire to select a subset of 200 to 300 of the 400 POTWs to participate in the POTW Influent PFAS Study and the NSSS's sampling programs.

Form numbers: None.

Respondents/affected entities: 400 POTWs with a daily design flow rate greater than or equal to 10 million gallons per day (MGD) and a service population greater than or equal to 50,000 people will be required to complete an electronic questionnaire. 200–300 of the 400 POTWs will be required to conduct wastewater and sewage sludge sampling.

Respondent's obligation to respond: Mandatory (Clean Water Act Section 308).

Estimated number of respondents: 400 (total).

Frequency of response: One-time data collection.

Total estimated burden: 25,640 hours. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$5,486,816 (one-time cost), which includes \$3,891,520 in capital or operation & maintenance costs.

Changes in the estimates: This is a new data collection request and is a one-time temporary increase to the agency's burden.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2024-23474 Filed 10-9-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-12247-01-OMS]

Senior Executive Service Performance Review Board; Membership

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given of the membership of the U.S. Environmental Protection Agency (EPA) Performance Review Board for 2024.

FOR FURTHER INFORMATION CONTACT:

Lizabeth Engebretson, Acting Director, Strategic HR Insights Division, 3606R, Office of Human Resources Strategy, Office of Mission Support, U.S. Environmental Protection Agency, 1300 Pennsylvania Avenue NW, Washington, DC 20460, telephone number: (202) 564-0804, email address: engebretson.lizabeth@epa.gov.

SUPPLEMENTARY INFORMATION: Section 4314(c)(1) through (5) of title 5, U.S.C., requires each agency to establish in accordance with regulations prescribed by the Office of Personnel Management, one or more SES performance review boards. This board shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointment authority relative to the performance of the senior executive. Members of the 2024 EPA Performance Review Board are:

Denise Benjamin-Sirmons, Director, Office of Small and Disadvantaged Business Utilization, Office of the Administrator.

Erica Canzler, Director, National Enforcement Investigations Center, Office of Enforcement and Compliance Assurance.

Louis D'Amico, Associate Director for Science, Office of Science Advisor, Policy and Engagement, Office of Research and Development.

Jeffrey Dawson, Senior Science Advisor, Office of Chemical Safety and Pollution Prevention.

Lizabeth Engebretson, (Ex-Officio) Deputy Director, Strategic HR Insights Division, Office of Human Resources Strategy, Office of Mission Support.

Caroline Freeman, Director, Superfund and Emergency Management Division, Region 4.

Alice Gilliland, Deputy Director for Management, Center for Environmental Measurement and Modeling, Office of Research and Development.

Michael Harris, Director, Enforcement and Compliance Division, Region 5.

JuanCarlos Hunt, (Ex-Officio)
Director, Office of Civil Rights, Office of
the Administrator.

Meshell Jones-Peeler, Controller,
Office of the Chief Financial Officer.

Mara J. Kamen, (Ex-Officio) Director,
Office of Human Resources Strategy,
Office of Mission Support.

Wynne Miller, Deputy Director, Office
of Wastewater Management, Office of
Water.

Javier Laureano, Director, Water
Division, Region 2.

Madison Le, Director, Biopesticides
and Pollution Prevention Division,
Office of Chemical Safety and Pollution
Prevention.

Pamela Legare, Director, Office of
Acquisition Solutions, Office of Mission
Support.

David Lloyd, Director, Office of
Brownfields and Land Revitalization,
Office of Land and Emergency
Management.

Vickie Richardson, Director, Office of
Management and International Services,
Office of International and Tribal
Affairs.

Cheryl Seager, Director, Enforcement
and Compliance Assurance Division,
Region 6.

Helen Serassio, Associate General,
Cross-Cutting Issues Law Office, Office
of General Counsel.

Richard "Chet" Wayland, Director,
Air Quality Assessment Division, Office
of Air and Radiation.

Mara J. Kamen,

*EPA Deputy Chief Human Capital Officer and
Director, Office of Human Resources Strategy,
Office of Mission Support.*

[FR Doc. 2024-23425 Filed 10-9-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

**[EPA-HQ-OCFO-2024-0048; FRL-12333-
01-OMS]**

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Promoting Readiness and Enhancing Proficiency To Advance Reporting and Data (PREPARED) Program: Post- Award Reporting and Public Outreach Information Collections (New)

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection
Agency (EPA) has submitted an
information collection request (ICR),
Promoting Readiness and Enhancing

Proficiency to Advance Reporting and
Data (PREPARED) Program: Post-Award
Reporting and Public Outreach
Information Collections (EPA ICR
Number 2804.01, OMB Control Number
2090-NEW) to the Office of
Management and Budget (OMB) for
review and approval in accordance with
the Paperwork Reduction Act. This is a
request for approval of a new collection.
Public comments were previously
requested via the **Federal Register** on
February 22, 2024, during a 60-day
comment period. This notice allows for
an additional 30 days for public
comments.

DATES: Comments may be submitted on
or before November 12, 2024.

ADDRESSES: Submit your comments,
referencing Docket ID Number EPA-HQ-
OCFO-2024-0048 to EPA online using
www.regulations.gov (our preferred
method), by email to doCKET_OCFO@epa.gov, or by mail to: EPA Docket
Center, Environmental Protection
Agency, Mail Code 28221T, 1200
Pennsylvania Ave. NW, Washington, DC
20460.

EPA's policy is that all comments
received will be included in the public
docket without change including any
personal information provided, unless
the comment includes profanity, threats,
information claimed to be Confidential
Business Information (CBI) or other
information whose disclosure is
restricted by statute.

Submit written comments and
recommendations to OMB for the
proposed information collection within
30 days of publication of this notice to
www.reginfo.gov/public/do/PRAMain.
Find this particular information
collection by selecting "Currently under
30-day Review—Open for Public
Comments" or by using the search
function.

FOR FURTHER INFORMATION CONTACT: Alex
Valdez, Office of the Chief Financial
Officer, Environmental Protection
Agency, 1200 Pennsylvania Ave. NW,
Washington, DC 20460; email address:
valdez.alex@epa.gov; phone: 202-564-
1746.

SUPPLEMENTARY INFORMATION: This is a
request for approval of a new collection.
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.

Public comments were previously
requested via the **Federal Register**
February 22, 2024, during a 60-day
comment period (89 FR 13332). This
notice allows for an additional 30 days
for public comments. Supporting

documents, which explain in detail the
information that the EPA will be
collecting, are available in the public
docket for this ICR. The docket can be
viewed online at www.regulations.gov
or in person at the EPA Docket Center,
WJC West, Room 3334, 1301
Constitution Ave. NW, Washington, DC.
The telephone number for the Docket
Center is 202-566-1744. For additional
information about EPA's public docket,
visit <http://www.epa.gov/dockets>.

Abstract: To help expand historically
underserved and overburdened
communities' access to critical
resources, the U.S. Environmental
Protection Agency (EPA) developed the
Promoting Readiness and Enhancing
Proficiency to Advance Reporting and
Data (PREPARED) Program. The
evidence-building technical assistance
(TA) providers (thereafter referenced as
Providers) will operate in cooperative
agreements with EPA to remove barriers
and improve access for communities
who have applied for or received
financial assistance awards to tackle
their environmental justice concerns.
The Providers will deliver TA and
training that is intended to enhance
capacity in: grant application and
administration, collecting grant related
data; meeting federal post-award
reporting requirements; project
planning/design; and generating
information necessary for outcomes
assessment, evaluation, and
identification of opportunities for
improvement. With this Information
Collection Request (ICR), EPA seeks
authorization to collect post-award
information from each Provider to track
their progress. Collection of this
information enables EPA to assess and
manage the PREPARED program, which
ensures responsible stewardship of
public funds; rigorous evidence-based
learning and improvement; and
transparent accountability to the
American public. This ICR also requests
authorization for the Providers to collect
input and insights from communities
who seek to obtain technical assistance
services, as well as stakeholders who
have valuable experience and expertise
in community engagement and
empowerment. These information
collections will enable the Providers to
document local priorities, needs, and
norms to ensure that they develop
useful and relevant technical assistance
and training services. Furthermore,
feedback about these services will
enable the Providers to conduct self-
assessments to identify best practices
and areas for improvement.

Form Numbers: None.

Respondents/affected entities:
Recipients of financial assistance

awards from the Promoting Readiness and Enhancing Proficiency to Advance Reporting and Data (PREPARED) Program, community members, stakeholders.

Respondent's obligation to respond: Mandatory for grant recipients as per reporting requirements included in EPA regulations 2 CFR parts 200 and 1500, and voluntary for public outreach information collections via surveys and focus groups.

Estimated number of respondents: 12 grant recipients and 4680 members of the public (over 3 years).

Frequency of response: Grant recipients will submit quarterly progress reports. Public outreach information collections (via surveys and focus groups) will occur throughout the life of the PREPARED project, with no more than one response per instrument per respondent.

Total estimated burden: 3,234 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$116,142 (per year), there are no annualized capital or operation & maintenance costs.

Changes in the Estimates: This is a new collection.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024-23473 Filed 10-9-24; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0719; FR ID 252112]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might “further reduce the information collection burden for small business concerns with fewer than 25 employees.” The Commission may not conduct or sponsor a collection of information unless it displays a

currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before November 12, 2024.

ADDRESSES: Comments should be sent to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Your comment must be submitted into www.reginfo.gov per the above instructions for it to be considered. In addition to submitting in www.reginfo.gov also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to PRA@fcc.gov and to Nicole.Ongele@fcc.gov. Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418-2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the web page called “Currently Under Review,” (3) click on the downward-pointing arrow in the “Select Agency” box below the “Currently Under Review” heading, (4) select “Federal Communications Commission” from the list of agencies presented in the “Select Agency” box, (5) click the “Submit” button to the right of the “Select Agency” box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have

practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might “further reduce the information collection burden for small business concerns with fewer than 25 employees.”

OMB Control Number: 3060-0719.

Title: Quarterly Report of Local Exchange Carriers Listing Payphone Automatic Number Identifications (ANIs).

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 400 respondents; 1,600 responses.

Estimated Time per Response: 3.5 hours (8 hours for the initial submission; 2 hours per subsequent submission, for an average of 3.5 hours per response).

Frequency of Response: Quarterly reporting requirement, recordkeeping requirement, and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154, 201-205, 215, 218, 219, 220, 226 and 276 of the Communications Act of 1934, as amended.

Total Annual Burden: 5,600 hours.

Total Annual Cost: No cost.

Needs and Uses: The Commission adopted rules and policies governing the payphone industry under section 276(b)(1)(A) of the Telecommunications Act of 1996 (the Act) and established “a per call compensation plan to ensure that all payphone service providers are fairly compensated for each and every completed intrastate and interstate call.” Pursuant to this mandate, and as required by section 64.1310(d) of the Commission's rules, Local Exchange Carriers (LECs) must provide to carriers required to pay compensation pursuant to section 64.1300(a), a quarterly report listing payphone ANIs. Without provision of this report, resolution of disputed ANIs would be rendered very difficult. Carriers would not be able to discern which ANIs pertain to payphones and therefore would not be

able to ascertain which dial-around calls were originated by payphones for compensation purposes. There would be no way to guard against possible fraud. Without this collection, lengthy investigations would be necessary to verify claims. The report allows carriers to determine which dial-around calls are made from payphones. The information must be provided to third parties. The requirement would be used to ensure that LECs and the carriers required to pay compensation pursuant to 47 CFR 64.1300(a) of the Commission's rules comply with their obligations under the Telecommunications Act of 1996.

Federal Communications Commission.
Marlene Dortch,
Secretary, Office of the Secretary.
[FR Doc. 2024-23480 Filed 10-9-24; 8:45 am]
BILLING CODE 6712-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

[OMB No. 3064-0165]

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collections described below (OMB Control No. 3064-0165).

DATES: Comments must be submitted on or before December 9, 2024.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *Agency Website:* <https://www.fdic.gov/resources/regulations/federal-register-publications/>.
- *Email:* comments@fdic.gov. Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202-898-3767), Regulatory Counsel, MB-3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street NW), on business days between 7:00 a.m. and 5:00 p.m. All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted

to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Regulatory Counsel, 202-898-3767, mcabeza@fdic.gov, MB-3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

- Proposal to renew the following currently approved collection of information:*
- Title:* Pillar 2 Guidance—Advanced Capital Framework.
- OMB Number:* 3064-0165.
- Form Number:* None.
- Affected Public:* Insured state nonmember banks and certain subsidiaries of these entities.
- Burden Estimate:*

SUMMARY OF ESTIMATED ANNUAL BURDEN
[OMB No. 3064-0165]

Information Collection (IC) (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
Supervisory Guidance: Supervisory Process of Capital Adequacy (Pillar 2) Related to the Implementation of the Basel II Advanced Capital Framework (Voluntary).	Recordkeeping (Quarterly).	1	4	105:00	420
Total Annual Burden (Hours):					420

Source: FDIC.

General Description of Collection. In 2008, the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, and the FDIC issued a supervisory guidance document related to the supervisory review process of capital adequacy (Pillar 2) in connection with the implementation of the Basel II Advanced Capital Framework. Sections 37, 41, 43, and 46 of the guidance include possible information collections. Section 37 provides that banks should state clearly the definition of capital used in any aspect of its internal capital adequacy assessment process (ICAAP) and document any changes in the internal definition of capital. Section 41 provides that banks

should maintain thorough documentation of its ICAAP. Section 43 specifies that the board of directors should approve the bank's ICAAP, review it on a regular basis and approve any changes. Section 46 recommends that boards of directors periodically review the assessment of overall capital adequacy and analyze how measures of internal capital adequacy compare with other capital measures such as regulatory or accounting. There has been no change in the method or substance of this information collection, and the burden is unchanged from the 2021 burden estimate.

Request for Comment

Comments are invited on: (a) whether the collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information

technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on October 4, 2024.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024–23408 Filed 10–9–24; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than November 12, 2024.

A. Federal Reserve Bank of New York (Bank Applications Officer) 33 Liberty

Street, New York, New York 10045–0001. Comments can also be sent electronically to

Comments.applications@ny.frb.org:

1. *Banco BTG Pactual S.A., BTG Pactual G7 Holding S.A., BTG Pactual Holding Financeira Ltda., and BTG Pactual Holding Internacional S.A., all of Rio de Janeiro, Brazil; BTG Pactual Holding S.A., São Paulo, Brazil; BTG Pactual UK Holdco Limited, London, United Kingdom; and BTG Pactual Bancorp, LLC, New York, New York;* to become bank holding companies by acquiring M.Y. Safra Bank, FSB, also of New York, New York.

B. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to

Comments.applications@stls.frb.org:

1. *Oak Tree Financial Corporation, Inc., Rogers, Arkansas;* to become a bank holding company by acquiring Riverside Bank, Sparkman, Arkansas.

C. Federal Reserve Bank of Minneapolis (Mark Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291.

Comments can also be sent electronically to *MA@mpls.frb.org:*

1. *Stearns Financial Services, Inc. Employee Stock Ownership Plan and Trust, Saint Cloud, Minnesota;* to acquire up to 23.65 percent of the voting shares of Stearns Financial Services, Inc., and thereby indirectly acquire voting shares of Stearns Bank National Association, both of Saint Cloud, Minnesota, and Stearns Bank of Upsala, National Association, Upsala, Minnesota.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2024–23485 Filed 10–9–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and

Budget (OMB) approve the extension without change of the previously approved information collection project “Nursing Home Survey on Patient Safety Culture Database,” OMB No. 0935–0195. This information collection was previously published in the **Federal Register** on August 9th, 2024 and allowed 60 days for public comment. AHRQ received no substantive comments from members of the public. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by November 12, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Nursing Home Survey on Patient Safety Culture Database

In 1999, the Institute of Medicine called for healthcare organizations to develop a “culture of safety” such that their workforce and processes focus on improving the reliability and safety of care for patients (IOM, 1999; To Err is Human: Building a Safer Health System). To respond to the need for tools to assess patient safety culture in healthcare, AHRQ developed and pilot tested the Surveys on Patient Safety Culture® (SOPS®) Nursing Home Survey with OMB approval (OMB No. 0935–0132). The survey is designed to enable nursing homes to assess provider and staff perspectives about patient safety issues, medical error, and error reporting and includes 42 items that measure 12 composites of patient safety culture. AHRQ made the survey publicly available along with a Survey User's Guide and other toolkit materials in November 2008 on the AHRQ website.

The AHRQ SOPS Nursing Home Database consists of data from the AHRQ Nursing Home Survey on Patient Safety Culture and may include

reportable, non-required supplemental items. Nursing homes in the U.S. can voluntarily submit data from the survey to AHRQ through its contractor, Westat. The SOPS Nursing Home Database was developed by AHRQ in 2011 in response to requests from nursing homes interested in viewing their organizations' patient safety culture survey results. Organizations submitting data receive a feedback report, as well as a report on the aggregated, de-identified findings of the other nursing homes submitting data. These reports are used to assist nursing home staff in their efforts to improve patient safety culture in their organizations.

The SOPS Nursing Home Survey and the SOPS Nursing Home Database support AHRQ's goals of promoting improvements in the quality and safety of healthcare in nursing home settings. The survey, toolkit materials, and database results are all made publicly available on AHRQ's website. Technical assistance is provided by AHRQ through its contractor at no charge to nursing homes, to facilitate the use of these materials for nursing home patient safety and quality improvement.

The nursing home survey and database have the following goals:

- Promote improvements in the quality and safety of healthcare in nursing home settings,
- Present results from nursing homes that voluntarily submit their data,
- Provide data to nursing homes to facilitate internal assessment and learning in the patient safety improvement process, and
- Provide supplemental information to help nursing homes identify their strengths and areas with potential for improvement in patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat,

pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services; quality measurement and improvement; and database development. 42 U.S.C 299a(a)(1), (2), and (8).

Method of Collection

To achieve the goal of this project the following activities and data collections will be implemented:

(1) *Eligibility and Registration Form*—The nursing home (or parent organization) point-of-contact (POC) completes a number of data submission steps and forms, beginning with the completion of an online Eligibility and Registration Form. The purpose of this form is to collect basic demographic information about the nursing home and initiate the registration process.

(2) *Nursing Home Site Information*—The purpose of the site information form, completed by the nursing home POC, is to collect background characteristics of the nursing home. This information will be used to analyze data collected with the SOPS Nursing Home Survey.

(3) *Data Use Agreement*—The purpose of the data use agreement, completed by the nursing home POC, is to state how data submitted by nursing homes will be used and provides confidentiality assurances.

(4) *Data File(s) Submission*—POCs upload their data file(s) using the data file specifications, to ensure that users submit their data in a standardized way (e.g., variable names, order, coding, formatting). The number of submissions to the database is likely to vary from

submission period to submission period because nursing homes do not administer the survey and submit data every database year. Data submission is typically handled by one POC who is either a corporate level healthcare manager for a Quality Improvement Organization (QIO), a survey vendor who contracts with a nursing home to collect their data, or a nursing home Director of Nursing or nurse manager. POCs submit data on behalf of 1 nursing home, on average, because many nursing homes are part of a QIO or larger nursing home or health system that includes many nursing home sites, or the POC is a vendor that is submitting data for multiple nursing homes.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the database. An estimated 50 POCs, each representing an average of 1 individual nursing home each, will complete the database submission steps and forms. Each POC will submit the following:

1. Eligibility and registration form (completion is estimated to take about 3 minutes).
2. Data Use Agreement (completion is estimated to take about 3 minutes).
3. Nursing Home Site Information Form (completion is estimated to take about 5 minutes).
4. Survey data submission will take an average of one hour.

The total annual burden hours are estimated to be 60 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be \$2,903 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/POCs	Number of responses per POC	Hours per response	Total burden hours
1. Eligibility/Registration Form	50	1	3/60	3
2. Data Use Agreement	50	1	3/60	3
3. Nursing Home Site Information Form	50	1	5/60	4
4. Data Files Submission	50	1	1	50
Total	NA	NA	NA	60

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Total burden hours	Average hourly wage rate *	Total cost burden
1. Eligibility/Registration Forms	3	\$48.43	\$146
2. Data Use Agreement	3	48.43	146
3. Nursing Home Site Information Form	4	48.43	194

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Total burden hours	Average hourly wage rate *	Total cost burden
4. Data Files Submission	50	48.43	2,422
Total	61	NA	2,907

* Mean hourly wage rate of \$48.43 for Medical and Health Services Managers (SOC code 11–9111) was obtained from the May 2023 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 623000—Nursing and Residential Care Facilities located at https://www.bls.gov/oes/current/naics3_623000.htm.

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ’s information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ’s health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency’s subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: October 3, 2024.

Marquita Cullom,
Associate Director.

[FR Doc. 2024–23429 Filed 10–9–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[CMS–1800–N4]

Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program Final Guidance

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing

the availability of CMS’ final guidance for the second cycle of the Medicare Drug Price Negotiation Program and manufacturer effectuation of the maximum fair price in 2026 and 2027 for the implementation of the Inflation Reduction Act. This and other Inflation Reduction Act-related guidance can be viewed on the dedicated Inflation Reduction Act section of the CMS website at <https://www.cms.gov/inflation-reduction-act-and-medicare/>.

ADDRESSES: Inquiries related to the final guidance should be sent to IRAREbateandNegotiation@cms.hhs.gov with the relevant subject line, “Medicare Drug Price Negotiation Program Final Guidance.”

SUPPLEMENTARY INFORMATION: The Inflation Reduction Act was signed into law on August 16, 2022. Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (Pub. L. 117–169) established the Medicare Drug Price Negotiation Program (hereafter the “Negotiation Program”) to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act (hereafter “the Act”) as added by sections 11001 and 11002 of the IRA. The final guidance summarizes and addresses comments received on the draft guidance issued on May 3, 2024 and describes how CMS intends to implement the Negotiation Program for Initial Price Applicability Year 2027 (January 1, 2027 to December 31, 2027), and specifies the requirements for manufacturer effectuation of the MFPs in 2026 and 2027. To obtain copies of the Negotiation Program final guidance and other Inflation Reduction Act-related documents, please access the CMS Inflation Reduction Act website by copying and pasting the following web address into your web browser: <https://www.cms.gov/inflation-reduction-act-and-medicare/>. If interested in receiving CMS Inflation Reduction Act updates by email, individuals may sign up for CMS Inflation Reduction Act’s email updates at <https://www.cms.gov/About-CMS/>

Agency-Information/Aboutwebsite/EmailUpdates. The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Evell J. Barco Holland,
Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–23418 Filed 10–9–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families****Proposed Information Collection Activity; Financing for Early Care and Education: Quality and Access for All–Case Studies (New Collection)**

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services seeks approval to collect information to deepen our understanding of Head Start programs’ funding approaches, as well as how the use of multiple funding sources within a single Head Start program may be associated with the delivery of Head Start’s comprehensive services and early care and education (ECE) funding landscapes within states. Interviews will be conducted with Head Start staff, as well as state and local/regional staff knowledgeable about and/or directly responsible for ECE financial decision making and/or funding source administration. Existing documents from Head Start programs and ECE agencies will also be reviewed to further contextualize interview data.

DATES: *Comments due* December 9, 2024. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing OPREinfocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed data collection builds upon prior survey work (Office of Management and Budget (OMB) #0970–0623) and seeks to better understand Head Start programs' use of multiple funding sources to support high-quality programming, as well as the state and local/regional policy contexts that influence their decision making. The data collection effort will consist of two studies: Study 1 will focus on coordination, or lack thereof, between the state level and the Head Start program level; Study 2 will focus on coordination, or lack thereof,

between the local level (region/county, city/municipality) and the Head Start program level. To capture the diversity of state ECE funding landscapes, both studies will examine coordination within: (A) states that combine ECE funding sources at the state level and (B) states that do not combine ECE funding sources at the state level.

Studies 1 and 2 will both include semi-structured interviews with staff within Head Start programs and state government agencies, and Study 2 will also include interviews with staff within local/regional coordinating entities (LCEs). The interviews will probe on approaches to using multiple funding sources at state, local/regional, and Head Start program levels, including how Head Start programs use multiple funding sources to support high-quality programming, how Head Start program funding approaches are shaped by system-level approaches and structures, and the implications of using multiple funding sources for access, quality, and equity in ECE programming. Because of slight differences in the ECE funding landscape across states that do and do

not combine funding at the state level, different interview protocols have been created within each study for state agency staff in states that do combine funding at the state level and staff in states that do not combine funding at the state level. Similarly, separate protocols were created for use in Head Start programs that do or do not use multiple funding sources. There is a single interview protocol for staff of LCEs with statutorily defined ECE financing authority.

Interviewers will also request and collect existing policy and/or budget-related documentation that may further contextualize respondent accounts and perspectives.

The resulting insights will inform ACF about the implementation of different funding models supporting Head Start programs, the facilitators that support and challenges that deter the use of multiple funding sources, and potential associations with program quality.

Respondents: Head Start program staff, State ECE staff, local/regional coordinating entity staff.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Final Recruitment Script— <i>Head Start Staff</i>	86	1	.5	43	21.5
Final Recruitment Script— <i>Local/Regional Staff</i>	42	1	.5	21	10.5
Final Recruitment Script— <i>State ECE Agency Staff</i>	56	1	.5	28	14
Study 1—Head Start Program Staff Interview Guide— <i>programs that use multiple funding sources</i>	16	1	1.5	24	12
Study 1—Head Start Program Staff Interview Guide— <i>programs that do not use multiple funding sources</i>	16	1	1.5	24	12
Study 1—State ECE Agency Staff Interview Guide— <i>states that combine funding at the state level</i>	6	1	1.5	9	4.5
Study 1—State ECE Agency Staff Interview Guide— <i>states that do not combine funding at the state level</i>	6	1	1.5	9	4.5
Study 2—Head Start Program Staff Interview Guide— <i>programs that use multiple funding sources and are in states that have LCEs</i>	16	1	1.5	24	12
Study 2—Head Start Program Staff Interview Guide— <i>programs that do not use multiple funding sources and are in states that have LCEs</i>	16	1	1.5	24	12
Study 2—Local Coordinating Entity Staff Interview Guide for states with LCEs	24	1	1.5	36	18
Study 2—State ECE Agency Staff Interview Guide— <i>states that combine funding at the state level and have LCEs</i>	12	1	1.5	18	9
Study 2—State ECE Agency Staff Interview Guide— <i>states that do not combine funds at the state level and have LCEs</i>	12	1	1.5	18	9

Estimated Total Annual Burden Hours: 139 hours.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be

collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 9835; 42 U.S.C. 9844.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–23479 Filed 10–9–24; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Cardiovascular Differentiation and Development.

Date: November 6, 2024.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4136, Bethesda, MD 20892, 301-435-0904, sara.ahlgren@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Neurodevelopment, Oxidative Stress, and Synaptic Plasticity Fellowship Study Section.

Date: November 7–8, 2024.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Washington Plaza Hotel, 10 Thomas Circle NW, Washington, DC 20005.

Contact Person: Robert C. Elliott, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5190, MSC 7846, Bethesda, MD 20892, 301-435-3009, elliottro@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Kidney and Urological Sciences.

Date: November 7–8, 2024.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: North Bethesda Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Ganesan Ramesh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301-827-5467, ganesan.ramesh@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Social Psychology and Interpersonal Processes Across the Lifecourse.

Date: November 7–8, 2024.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: David E. Pollio, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1006F, Bethesda, MD 20892, (301) 594-4002, polliode@csr.nih.gov.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Adaptive Immunity Study Section.

Date: November 7–8, 2024.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Liying Guo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, (301) 827-7728, lguo@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Chemistry, Biochemistry & Biophysics.

Date: November 7–8, 2024.

Time: 8:30 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Address: The Bethesda Hotel, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Dennis Pantazatos, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-2381, dennis.pantazatos@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Neuroscience Assays, Diagnostics, Instrumentation, and Interventions.

Date: November 7–8, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aurea D. De Sousa, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, Bethesda, MD 20892, (301) 827-6829, aurea.desousa@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR Panel: Multi-Sectoral Preventive Interventions that Address Social Determinants of Health in Populations that Experience Health Disparities.

Date: November 7–8, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lauren Susan Penney, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-1968, penneyls@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Medical Imaging Investigations.

Date: November 7, 2024.

Time: 9:00 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301-435-2392, masoodk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Members Conflict: Topics in Hepatobiliary Pathobiology and Environmental Toxicology.

Date: November 7–8, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Atul Sahai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892, 301-435-1198, sahaia@csr.nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Tissue Engineering Study Section.

Date: November 7–8, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Hybrid Meeting).

Contact Person: Thomas Zeyda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-6921, thomas.zeyda@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 7, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-23494 Filed 10-9-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute on Drug Abuse; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute on Drug Abuse. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Drug Abuse, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute on Drug Abuse.

Date: October 22, 2024.

Time: 10:00 a.m. to 4:45 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Drug Abuse, NIH, Biomedical Research Center, 251 Bayview Boulevard, Baltimore, MD 21224.

Meeting Format: Virtual Meeting.

Contact Person: Megan E. Bollinger, M.S., Management Analyst, Office of the Scientific Director, National Institute on Drug Abuse, 251 Bayview Boulevard, Suite 200, Baltimore, MD 21224, (443) 740-2466, Megan.Bollinger@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 7, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-23493 Filed 10-9-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed).

Date: November 12-14, 2024.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20892, (240) 669-5931, jakesse@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 7, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-23491 Filed 10-9-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: November 7, 2024.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Sandip Bhattacharyya, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42, Rockville, MD 20892 (240) 292-0189, sandip.bhattacharyya@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 7, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-23492 Filed 10-9-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard**

[Docket No. USCG-2024-0882]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625-0092

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and

Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0092, Sewage and Graywater Discharge Records for Certain Cruise Vessels Operating on Alaskan Waters; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before December 9, 2024.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2024–0882] to the Coast Guard using the Federal eRulemaking 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.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, fax 202–372–8405, or email hqs-dg-m-cg-61-pii@uscg.mil for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.*, chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection’s purpose, the Collection’s likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of

the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, USCG–2024–0882, and must be received by December 9, 2024.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <https://www.regulations.gov> and can be viewed by following that website’s instructions. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

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 in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Sewage and Graywater Discharge Records for Certain Cruise Vessels Operating on Alaskan Waters.
OMB Control Number: 1625–0092.

Summary: To comply with the title XIV of Public Law 106–554, this information collection is needed to enforce sewage and graywater discharge requirements from certain cruise ships operating on Alaskan waters.

Need: 33 CFR part 159 subpart E prescribe regulations governing the discharge of sewage and graywater from cruise vessels, requires sampling and testing of sewage and graywater discharges, and establishes reporting and recordkeeping requirements.

Forms: Not applicable.

Respondents: Owners, operators, and masters of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 358 hours to 555 hours a year, due to an increase in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 3, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–23470 Filed 10–9–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0785]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0014

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0014, Request for Designation and Exemption of Oceanographic Research Vessels; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before December 9, 2024.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2024–0785] to the Coast Guard using the Federal eRulemaking 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.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703

Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, fax 202–372–8405, or email hqs-dg-m-cg-61-pii@uscg.mil for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.*, chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, USCG–2024–0785, and must be received by December 9, 2024.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public

comments, are in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

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 in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Request for Designation and Exemption of Oceanographic Research Vessels.

OMB Control Number: 1625–0014.

Summary: This collection requires submission of specific information about a vessel in order for the vessel to be designated as an Oceanographic Research Vessel (ORV).

Need: 46 U.S.C. 2113 authorizes the Secretary of the Department of Homeland Security to exempt ORVs, by regulation, from provisions of Subtitle II, of Title 46, Shipping, of the United States Code, concerning maritime safety and seaman's welfare laws. This information is necessary to ensure a vessel qualifies for the designation of ORV under 46 CFR part 3 and 46 CFR part 14, subpart D.

Forms: None.

Respondents: Owners and operators of certain vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 36 hours to 37 hours a year, due to an increase in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 3, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–23475 Filed 10–9–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2024–0002; Internal Agency Docket No. FEMA–B–2461]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before January 8, 2025.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location <https://hazards.fema.gov/femaportal/prelimdownload> and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

You may submit comments, identified by Docket No. FEMA–B–2461, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacbibit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and

Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacibit@fema.dhs.gov; or visit the FEMA Mapping and Insurance eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are

used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information

regarding the SRP process can be found online at https://www.floodsrp.org/pdfs/srp_overview.pdf.

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location https://hazards.fema.gov/femaportal/prelim_download and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison. (Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Nicholas A. Shufro,

Assistant Administrator (Acting) for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Richland County, North Dakota and Incorporated Areas Project: 18-05-0006S Preliminary Date: March 20, 2024	
Township of Abercrombie	Abercrombie Township Hall, 111 Galchutte Avenue, Wahpeton, ND 58075.

[FR Doc. 2024-23453 Filed 10-9-24; 8:45 am]
BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2008-0010]

Board of Visitors for the National Fire Academy

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The Board of Visitors for the National Fire Academy (Board) will meet virtually on Monday, December 2, 2024. The meeting will be open to the public.

DATES: The meeting will take place on Monday, December 2, 2024, 1 p.m. to 3 p.m. Eastern Standard Time (EST). Please note that the meeting may close

early if the Board has completed its business.

ADDRESSES: Members of the public who wish to participate in the virtual conference should contact Deborah Gartrell-Kemp as listed in the **FOR FURTHER INFORMATION CONTACT** section by close of business on November 22, 2024, to obtain the call-in number and access code for the December 2nd virtual meeting. The Board is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact Deborah Gartrell-Kemp as listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Board as listed in the **SUPPLEMENTARY INFORMATION** section. Participants seeking to have their comments considered during the meeting should submit them in advance or during the public comment segment. Comments submitted up to 30 days after the

meeting will be included in the public record and may be considered at the next meeting. Comments submitted in advance must be identified by Docket ID FEMA-2008-0010 and may be submitted by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Electronic Delivery:** Email Deborah Gartrell-Kemp at Deborah.Gartrell-Kemp@fema.dhs.gov no later than November 22, 2024, for consideration at the December 2, 2024, meeting.

Instructions: All submissions received must include the words "Federal Emergency Management Agency" and the Docket ID for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided. You may wish to view the Privacy and Security Notice via a link on the homepage of <https://www.regulations.gov>.

Docket: For access to the docket and to read background documents or comments received by the National Fire

Academy Board of Visitors, go to <http://www.regulations.gov>, insert “FEMA–2008–0010” in the search box and then click “Search.”

FOR FURTHER INFORMATION CONTACT:

Designated Federal Officer: Eriks Gabliks, telephone (301) 447–1308, email Eriks.Gabliks@fema.dhs.gov.

Logistical Information: Deborah Gartrell-Kemp, telephone (301) 447–7230, email Deborah.Gartrell-Kemp@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: The Board will meet virtually on Monday, December 2, 2024. The meeting will be open to the public. Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. chapter 10.

Purpose of the Board

The purpose of the Board is to review annually the programs of the National Fire Academy (Academy) and advise the Administrator of the Federal Emergency Management Agency (FEMA), through the United States Fire Administrator, on the operation of the Academy and any improvements therein that the Board deems appropriate. In carrying out its responsibilities, the Board examines Academy programs to determine whether these programs further the basic missions that are approved by the Administrator of FEMA, examines the physical plant of the Academy to determine the adequacy of the Academy’s facilities, and examines the funding levels for Academy programs. The Board submits a written annual report through the United States Fire Administrator to the Administrator of FEMA. The report provides detailed comments and recommendations regarding the operation of the Academy.

Agenda

On Monday, December 2, 2024, there will be four sessions, with deliberations and voting at the end of each session as necessary:

1. The Board will discuss United States Fire Administration Data, Emergency Medical Services (EMS), Research, Prevention and Response.
2. The Board will discuss deferred maintenance and capital improvements on the National Emergency Training Center campus and Fiscal Year 2025 and beyond Budget Request/Budget Planning.
3. The Board will deliberate and vote on recommendations on Academy program activities to include developments, deliveries, staffing, admissions, and strategic plan.
4. There will also be an update on the Board of Visitors Subcommittee Groups

for the Professional Development Initiative Update and the National Fire Incident Report System.

There will be a 10-minute public comment period after each agenda item and each speaker will be given no more than 2 minutes to speak. Please note that the public comment period may end before the time indicated following the last call for comments. Contact Deborah Gartrell-Kemp to register as a speaker. Meeting materials will be posted by November 15, 2024, at <https://www.usfa.fema.gov/nfa/about/board-of-visitors.html>.

Eriks J. Gabliks,

Superintendent, National Fire Academy, United States Fire Administration, Federal Emergency Management Agency.

[FR Doc. 2024–23478 Filed 10–9–24; 8:45 am]

BILLING CODE 9111–74–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–OC–2024–N051;
FXGO16600926000–245–FF09X60000]

Hunting and Wildlife Conservation Council; Request for Nominations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Request for nominations.

SUMMARY: The U.S. Department of the Interior and the Department of Agriculture are seeking nominations to the Hunting and Wildlife Conservation Council (Council) to fill one vacancy for a representative from a state fish and wildlife management agency. The Council provides recommendations to the Federal Government, through the Secretary of the Interior and the Secretary of Agriculture, regarding the establishment and implementation of existing and proposed policies and authorities with regard to wildlife and habitat conservation endeavors that benefit wildlife resources; encourage partnership among the public, sporting conservation organizations, wildlife-associated recreation interests, and Federal, State, Tribal, and territorial governments; and benefit fair-chase recreational hunting and safe recreational shooting sports.

DATES: Nominations for the Council must be submitted by November 12, 2024.

ADDRESSES: You may submit nominations via email to doug_hobbs@fws.gov.

FOR FURTHER INFORMATION CONTACT: Douglas Hobbs, Designated Federal

Officer, by email at doug_hobbs@fws.gov, or by telephone at 703–358–2336. 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 Council is established under the authority of the Secretaries of the Department of the Interior (DOI) and the Department of Agriculture (Secretaries) and is regulated by the Federal Advisory Committee Act, as amended (FACA; 5 U.S.C. ch. 10). The Council’s duties are strictly advisory and consist of, but are not limited to, providing recommendations for implementation of Executive Order (E.O.) 13443, Facilitation of Hunting Heritage and Wildlife Conservation; E.O. 14008, Tackling the Climate Crisis at Home and Abroad; and Secretarial Order (S.O.) 3362, Improving Habitat Quality in Western Big Game Winter Range and Migration Corridors. Duties include, but are not limited to:

A. Assessing and quantifying implementation of E.O. 13443, E.O. 14008, and S.O. 3362 across relevant departments, agencies, and offices and making recommendations to enhance and expand their implementation as identified;

B. Making recommendations regarding policies and programs that accomplish the following objectives:

1. Conserve and restore wetlands, grasslands, forests, and other important wildlife habitats, and improve management of rangelands and agricultural lands to benefit wildlife;
2. Promote opportunities for fair-chase hunting and safe recreational shooting sports and wildlife-associated recreation on public and private lands;
3. Encourage hunting and recreational shooting sports safety, including by developing sighting-in ranges on public lands;
4. Recruit and retain hunters;
5. Increase public awareness of the importance of wildlife conservation and the social and economic benefits of fair-chase hunting, safe recreational shooting sports, and wildlife-associated recreation; and
6. Encourage coordination among the public; the hunting and shooting sports communities; wildlife conservation groups; wildlife-associated recreation interests; and Federal, State, Tribal, and territorial governments.

The Secretaries appoint members and their alternates to the Council to serve up to a 3-year term. The Council will not exceed 18 discretionary primary members, up to 18 alternate members, and 4 ex officio members. Ex officio members include:

- Secretary of the Interior or designated DOI representatives;
- Secretary of Agriculture or designated Department of Agriculture representatives; and
- Executive Director, Association of Fish and Wildlife Agencies.

The Secretaries select remaining members from among, but not limited to, the organization/interests listed below. These members must be senior-level representatives of their organization and/or have the ability to represent their designated constituencies.

- State fish and wildlife management agencies;
- Wildlife and habitat conservation/management organizations;
- Upland bird hunting organizations;
- Waterfowl hunting organizations;
- Big game hunting organizations;
- Shooting sports interests;
- Archery interests;
- Wildlife-associated recreation interests;
- Tourism, outfitter, and/or guide industries related to hunting and/or wildlife conservation;
- Tribal resource management organizations;
- Agriculture interests;
- Ranching interests; and
- Veterans' service organizations.

Vacancies To Fill

Nominations are sought to fill one primary member vacancy to represent State fish and wildlife management agencies.

Nomination Method and Information

Nominations should include a cover letter or email and a resume providing an adequate description of the nominee's qualifications, including information that would enable DOI to make an informed decision regarding meeting the membership requirements of the Council and to permit DOI to contact a potential member.

Members of the Council serve without compensation. However, while away from their homes or regular places of business, Council and subcommittee members engaged in Council or subcommittee business that the DFO approves may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by 5 U.S.C. 5703, in the same manner as persons employed intermittently in Federal Government service.

Authority 5 U.S.C. ch. 10.

Lesli Gray,

Assistant Director—Office of Communications.

[FR Doc. 2024–23476 Filed 10–9–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[256A2100DD/AAKC001030/
AOA501010.999900; OMB Control Number
1076–0160]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Verification of Indian Preference for Employment in the BIA and the IHS

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Affairs (BIA) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before November 12, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection request (ICR) should be sent within 30 days of publication of this notice to the Office of Information and Regulatory Affairs (OIRA) through https://www.reginfo.gov/public/do/PRA/icrPublicCommentRequest?ref_nbr=202405-1076-005 or by visiting <https://www.reginfo.gov/public/do/PRAMain> and selecting “Currently under Review—Open for Public Comments” and then scrolling down to the “Department of the Interior.”

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Steven Mullen, Information Collection Clearance Officer, Office of Regulatory Affairs and Collaborative Action—Indian Affairs, U.S. Department of the Interior, 1001 Indian School Road NW, Suite 229, Albuquerque, New Mexico 87104; comments@bia.gov; (202) 924–2650. 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. You may also view the ICR at <https://www.reginfo.gov/public/Forward?>

SearchTarget=PRA&textfield=1076-0160.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on June 21, 2024 (89 FR 52076). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

- (1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The BIA is seeking renewal of the approval for the information

collection conducted under 25 U.S.C. 43, 36 Stat. 472, inter alia, and implementing regulations, at 25 CFR part 5, regarding verification of Indian preference for employment. The purpose of Indian preference is to encourage qualified Indian persons to seek employment with the BIA and the Indian Health Service (IHS) by offering preferential treatment to qualified candidates of Indian heritage. The BIA collects the information to ensure compliance with Indian preference hiring requirements. The information collection relates only to individuals applying for employment with the BIA and/or IHS. The tribe's involvement is limited to verifying membership information submitted by the applicant. The collection of information allows certain persons who are of Indian descent to receive preference when appointments are made to vacancies in positions with the BIA and the IHS as well as in any unit that has been transferred intact from the BIA to a Bureau or office within the Department of the Interior or the Department of Health and Human Services and that continues to perform functions formerly performed as part of the BIA and the IHS. You are eligible for preference if (a) you are a member of a federally recognized Indian tribe; (b) you are a descendent of a member and you were residing within the present boundaries of any Indian reservation on June 1, 1934; (c) you are an Alaska native; or (d) you possess one-half degree Indian blood derived from tribes that are indigenous to the United States.

Title of Collection: Verification of Indian Preference for Employment in the BIA and the IHS.

OMB Control Number: 1076-0160.

Form Number: BIA 4432.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Qualified Indian persons who are seeking preference in employment with the BIA and the IHS.

Total Estimated Number of Annual Respondents: 5,000 per year, on average.

Total Estimated Number of Annual Responses: 5,000 per year, on average.

Estimated Completion Time per Response: 30 minutes.

Total Estimated Number of Annual Burden Hours: 2,500 hours.

Respondent's Obligation: A response is required to obtain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: \$7,640.

Authority

An agency may not conduct or sponsor and a person is not required to

respond to a collection of information unless it displays a currently valid OMB control number. The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Steven Mullen,

*Information Collection Clearance Officer,
Office of Regulatory Affairs and Collaborative
Action—Indian Affairs.*

[FR Doc. 2024-23405 Filed 10-9-24; 8:45 am]

BILLING CODE 4337-15-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[245D0102DM DS61100000
DLSN00000.000000 DX61101; OMB Control
Number 1094-0001]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; the Alternatives Process in Hydropower Licensing

AGENCY: Office of the Secretary, Office of Environmental Policy and Compliance, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of the Secretary, Office of Environmental Policy and Compliance, Department of the Interior (we, OS-OEPC) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before November 12, 2024.

ADDRESSES: Send written comments on this information collection request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at OIRA_Submission@omb.eop.gov; or via facsimile to (202) 395-5806. Please provide a copy of your comments to National Environmental Policy Act and Environmental Review Coordination Division, Office of Environmental Policy and Compliance, U.S. Department of the Interior, MS 2629-MIB, 1849 C Street NW, Washington, DC 20240; or by email to Environmental_Review@ios.doi.gov. Please reference OMB Control Number 1094-0001 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Shawn Alam, National Environmental Policy Act and Environmental Review Coordination Division by email at Environmental_Review@ios.doi.gov, or by telephone at (771) 216-5846. You may also view the

ICR at <http://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

On June 7, 2024, we published a **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information (89 FR 48673). We received no comments in response to that notice.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) is the collection necessary to the proper functions of the OS-OEPC; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the OS-OEPC enhance the quality, utility, and clarity of the information to be collected; and (5) how might the OS-OEPC minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The OMB regulations at 5 CFR part 1320, which implement the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*, require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8 (d)).

On November 23, 2016, the Departments of Agriculture, the Interior, and Commerce published a final rule on the March 31, 2015 revised interim final rule to the interim rule originally published in November 2005 at 7 CFR

part 1, 43 CFR part 45, and 50 CFR part 221, to implement section 241 of the Energy Policy Act of 2005 (EP Act), Public Law 109–58, enacted on August 8, 2005. Section 241 of the EP Act added a new section 33 to the Federal Power Act (FPA), 16 U.S.C. 823d, that allowed the license applicant or any other party to the license proceeding to propose an alternative to a condition or prescription that one or more of the Departments develop for inclusion in a hydropower license issued by the Federal Energy Regulatory Commission (FERC) under the FPA. This provision required that the Department of Agriculture, the Department of the Interior, and the Department of Commerce collect the information covered by 1094–0001.

Under FPA section 33, the Secretary of the Department involved must accept the proposed alternative if the Secretary determines, based on substantial evidence provided by a party to the license proceeding or otherwise available to the Secretary, (a) that the alternative condition provides for the adequate protection and utilization of the reservation, or that the alternative prescription will be no less protective than the fishway initially proposed by the Secretary, and (b) that the alternative will either cost significantly less to implement or result in improved operation of the project works for electricity production.

In order to make this determination, the regulations require that all of the following information be collected: (1) a description of the alternative, in an equivalent level of detail to the Department's preliminary condition or prescription; (2) an explanation of how the alternative: (i) if a condition, will provide for the adequate protection and utilization of the reservation; or (ii) if a prescription, will be no less protective than the fishway prescribed by the bureau; (3) an explanation of how the alternative, as compared to the preliminary condition or prescription, will: (i) cost significantly less to implement; or (ii) result in improved operation of the project works for electricity production; (4) an explanation of how the alternative or revised alternative will affect: (i) energy supply, distribution, cost, and use; (ii) flood control; (iii) navigation; (iv) water supply; (v) air quality; and (vi) other aspects of environmental quality; and (5) specific citations to any scientific studies, literature, and other documented information relied on to support the proposal.

This notice of proposed renewal of an existing information collection is being published by the Office of Environmental Policy and Compliance,

Department of the Interior, on behalf of all three Departments, and the data provided below covers anticipated responses (alternative conditions/prescriptions and associated information) for all three Departments.

Title of Collection: 7 CFR part 1; 43 CFR part 45; 50 CFR part 221; The Alternatives Process in Hydropower Licensing.

OMB Control Number: 1094–0001.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Business or for-profit entities.

Total Estimated Number of Annual Respondents: 5.

Total Estimated Number of Annual Responses: 5.

Estimated Completion Time per Response: 500 hours.

Total Estimated Number of Annual Burden Hours: 2,500 hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: Once per alternative proposed.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Stephen G. Tryon,

Director, Office of Environmental Policy and Compliance.

[FR Doc. 2024–23481 Filed 10–9–24; 8:45 am]

BILLING CODE 4334–63–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1412]

Certain NAND Memory Devices and Electronic Devices Containing Same; Notice of the Commission's Determination Not To Review an Initial Determination Terminating the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's ("ALJ") initial determination ("ID") (Order No. 7) terminating the investigation based on a settlement agreement and withdrawal of the complaint.

FOR FURTHER INFORMATION CONTACT:

Edward S. Jou, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3316. 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: The Commission instituted this investigation on August 13, 2024, based on a complaint filed by MimirIP LLC of Dallas, Texas ("Mimir"). 89 FR 65931–32 (Aug. 13, 2024). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain NAND memory devices and electronic devices containing same by reason of infringement of certain claims of U.S. Patent Nos. 8,637,919; 9,245,962; and 10,896,918. The notice of investigation named as respondents: Micron Technology, Inc. ("Micron") of Boise, Idaho; Acer Inc. of New Taipei City, Taiwan; Acer America Corp. of San Jose, California; HP, Inc. of Palo Alto, California; Kingston Technology Company, Inc. of Fountain Valley, California; Lenovo Group Limited of Hong Kong, China; and Lenovo (United States) Inc. of Morrisville, North Carolina (collectively, "Respondents"). The Office of Unfair Import Investigations ("OUII") is also a party in this investigation.

On August 28, 2024, Mimir and Respondents filed a joint motion to terminate the investigation based on a settlement between Mimir and Micron that resolves all issues as to all Respondents in this investigation. On September 5, 2024, OUII filed a response in support of the motion. On September 6, 2024, the ALJ issued Order No. 6 requesting additional clarification regarding the motion. On September 10, 2024, Mimir and Micron jointly filed a supplement to the motion stating that Mimir requests termination of the investigation based on withdrawal of

the complaint with respect to the respondents other than Micron.

On September 12, 2024, the ALJ issued the subject ID granting the joint motion to terminate the investigation. The ALJ found that the motion complied with the requirements of Commission Rule 210.21(b)(1) (19 CFR 210.21(b)(1)) with respect to the termination of Micron based on a settlement agreement, and the motion complied with the requirements of Commission Rule 210.21(a)(1) (19 CFR 210.21(a)(1)) with respect to the termination of the remaining respondents by withdrawal of the complaint. No petitions for review of the ID were filed.

The Commission has determined not to review the subject ID. The investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on October 4, 2024.

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: October 4, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024-23403 Filed 10-9-24; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1352]

Certain Selective Thyroid Hormone Receptor-Beta Agonists, Processes for Manufacturing or Relating to Same, and Products Containing Same; Notice of Request for Submissions on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on October 3, 2024, the presiding Chief Administrative Law Judge ("Chief ALJ") issued an Initial Determination on Violation of Section 337. The Chief ALJ also issued a Recommended Determination on remedy and bonding should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This

notice is soliciting comments from the public and interested government agencies only.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry. (19 U.S.C. 1337(d)(1)). A similar provision applies to cease and desist orders. (19 U.S.C. 1337(f)(1)).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: a limited exclusion order directed to certain selective thyroid hormone receptor-beta agonists, processes for manufacturing or relating to same, and products containing same, imported, sold for importation, and/or sold after importation by respondents Ascleitis Pharma Inc., Ascleitis Pharmaceuticals Co. Ltd., Ascleitis Bioscience Co., Ltd., Gannex Pharma Co., Ltd., and Jinzi Jason Wu (collectively, "Respondents"), and cease and desist orders against the Respondents. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public and interested government agencies are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public

interest in light of the Chief ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on October 3, 2024. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, 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 recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended 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 recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on November 4, 2024.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number ("Inv. No. 337-TA-1352") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, https://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) &

210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing and must be served in accordance with Commission Rule 210.4(f)(7)(ii)(A) (19 CFR 210.4(f)(7)(ii)(A)). 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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of 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: October 4, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024-23422 Filed 10-9-24; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1406]

Certain Memory Devices and Electronic Devices Containing the Same; Notice of a Commission Determination Not To Review an Initial Determination Terminating an Investigation Based on a Settlement Agreement; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined not to review an initial determination ("ID") (Order No. 10) of the presiding administrative law judge ("ALJ") granting a joint motion to terminate the investigation based on a settlement agreement. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT:

Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on July 9, 2024, based on a complaint filed by MimirIP LLC of Dallas, Texas ("Complainant" or "Mimir"). 89 FR 56406-407 (July 9, 2024). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain memory devices and electronic devices containing the same by reason of the infringement of certain claims of U.S. Patent Nos. 7,468,928; 7,579,846; and 8,036,053. *Id.* The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named as respondents Micron Technology Inc. of Boise, Idaho; Hewlett Packard Enterprise Co. of Spring, Texas; HP, Inc. of Palo Alto, California; Kingston Technology Company, Inc. of Fountain Valley, California; Lenovo Group Limited of Hong Kong; Lenovo (United States) Inc. of Morrisville, North Carolina; and Tesla Inc. of Austin, Texas. *Id.* The Office of Unfair Import Investigations ("Staff") is participating in the investigation for issues relating to the economic prong of the domestic industry requirement, remedy, and public interest only. EDIS Doc. ID 826262 (July 17, 2024).

The Commission previously terminated respondent Lenovo Group

Limited from this investigation and amended the complaint and the notice of investigation to add Lenovo PC HK Limited of Hong Kong and Lenovo Global Technology (United States) Inc. of Morrisville, North Carolina as respondents. Order No. 8 (Aug. 8, 2024), *unreviewed by* 89 FR 68645 (Aug. 27, 2024).

On August 27, 2024, Complainant and respondent Micron Technology, Inc. jointly moved for termination of this investigation in its entirety based on settlement agreements, which are "a [sublicense] agreement between Mimir and SK hynix Inc. and a patent license agreement between SK hynix and Micron." ID at 1 n. 1 (citing Mot. at 2). The joint motion notes that it is "based on an agreement between Mimir and SK hynix and an agreement between SK hynix and Micron, which 'collectively resolve all claims in the complaint asserted against all Respondents in this Investigation.'" *Id.* at 2 (citing Mot. at 2). The joint motion notes that it is not opposed by the non-moving respondents, Hewlett Packard Enterprise Co., HP Inc., Kingston Technology Company, Inc., Lenovo PC HK Limited, Lenovo Global Technology (United States) Inc., Lenovo (United States) Inc., and Tesla, Inc. On September 5, 2024, Staff filed a response supporting the joint motion. No other responses were filed.

On September 12, 2024, the presiding ALJ issued the subject ID granting the joint motion to terminate the investigation. Order No. 10 (Sept. 12, 2024). The subject ID finds that the joint motion complies with Commission Rule 210.21(b)(1) (19 CFR 210.21(b)) and that no extraordinary circumstances prevent granting the motion. The ID also finds that termination of the investigation based on settlement would not be contrary to the public interest.

No petitions for review of the ID were filed.

The Commission has determined not to review the subject ID (Order No. 10). The investigation is terminated.

The Commission vote for this determination took place on October 4, 2024.

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: October 4, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–23402 Filed 10–9–24; 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 Crafting Machines and Components Thereof*, DN 3774; 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 Cricut, Inc. on October 4, 2024. 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 crafting machines and components thereof. The complaint names as respondents: Hunan Sijiu Technology, Co. Ltd. of China; Hunan Sijiu Electronic Technology Co., Ltd. of

China; Guangdong Rongtu Technology Co., Ltd. of China; LiPing Zhan of China; SainStore Technology Co., Ltd. of China; Shanghai Sishun E-commerce Co., Ltd. of China; Shanghai Sishun Co., Ltd. of China; Bozhou Wanxingyu Technology Co. Ltd. of China; Bozhou Zhongdaxiang Technology Co., Ltd. of China; and Wuyi Bohai Electric Tools Co., Ltd. of China. The complainant requests that the Commission issue a limited exclusion order, a general 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 respondents, other interested parties, members of the public, and interested government agencies 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, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. 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. 3774") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures¹). 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 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

¹ Handbook for Electronic Filing Procedures: https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.

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: October 7, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–23444 Filed 10–9–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Salman Akbar, M.D.; Decision and Order

On January 27, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Salman Akbar, M.D., of Richmond, Virginia (Applicant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, Attachment E, at 1, 4. The OSC proposed the denial of Applicant's application for a DEA Certificate of Registration (registration), Control No. W22109452C, alleging that Applicant has committed acts that would render his registration inconsistent with the public interest. *Id.* at 1, 2 (citing 21 U.S.C. 823(g)(1),¹ 824(a)(4) 2).

The OSC notified Applicant of his right to file with DEA a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* at 2 (citing 21 CFR 1301.43). Here, Applicant filed a timely

answer and request for hearing on February 28, 2023,³ but ultimately withdrew his request for hearing on March 27, 2023. *See* RFAAX 1, Attachment F.⁴ On March 27, 2023, Chief Administrative Law Judge John J. Mulrooney, II, (the Chief ALJ) issued a Termination Order that terminated the proceedings. 21 CFR 1301.43(c) provides that, “[i]n the event . . . a person who has requested a hearing fails to plead . . . or otherwise defend, said party shall be deemed to be in default” By voluntarily withdrawing his hearing request, Respondent “fail[ed] to . . . otherwise defend.” 21 CFR 1301.43(c). Accordingly, Respondent is “deemed to be in default.” *Id.*; Default Provisions for Hearing Proceedings Relating to the Revocation, Suspension, or Denial of a Registration, 87 FR 68036 (Nov. 14, 2022).⁵ *See* RFAAX 1, Attachment G. “A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC].” 21 CFR 1301.43(e).

Further, “[i]n the event that a [registrant/applicant] . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67.” *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Applicant's default pursuant to 21 CFR 1301.43(c), (d), 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

I. Findings of Fact

The Agency finds that, in light of Applicant's default, the factual allegations in the OSC are admitted. Applicant is deemed to have admitted

that on March 2, 2020, DEA issued Applicant an Immediate Suspension Order and Order to Show Cause that suspended Applicant's previous DEA registration, Control No. BA5092856, and immediately rendered Applicant without authority to issue prescriptions for controlled substances. RFAAX 1, Attachment E, at 1–2; *see also* RFAAX 1, Attachment B. Further, on October 20, 2021, by Order of the then-Acting Administrator, Applicant's DEA registration, Control No. BA5092856, was revoked. RFAAX 1, Attachment E, at 2; *see also* RFAAX 1, Attachment C.

Nonetheless, Applicant is deemed to have admitted, and the Agency finds, that between on or about January 15, 2021, and on or about January 6, 2022, Applicant issued at least 17 prescriptions for controlled substances, including four prescriptions for oxycodone (a Schedule II controlled substance), two prescriptions for hydrocodone (a Schedule II controlled substance), five prescriptions for lorazepam (a Schedule IV controlled substance), two prescriptions for zolpidem (a Schedule IV controlled substance), one prescription for clonazepam (a Schedule IV controlled substance), two prescriptions for pregabalin (a Schedule V controlled substance), and one prescription for diazepam (a Schedule IV controlled substance). RFAAX 1, Attachment E, at 2; *see also* RFAAX 1, Attachment D. Applicant is deemed to have admitted, and the Agency finds, that each of these 17 prescriptions was issued without a DEA registration and outside the usual course of professional practice. *Id.*

II. Discussion

A. The Five Public Interest Factors

Pursuant to section 303(g)(1) of the CSA, “[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.” 21 U.S.C. 823(g)(1). Section 303(g)(1) further provides that an application for a practitioner's registration may be denied upon a determination that “the issuance of such registration . . . would be inconsistent with the public interest.” *Id.* In making the public interest determination, the CSA requires consideration of the following factors:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(C) The applicant's conviction record under Federal or State laws relating to the

² All contract personnel will sign appropriate nondisclosure agreements.

³ Electronic Document Information System (EDIS): <https://edis.usitc.gov>

¹ Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

² Prior Agency decisions have addressed whether it is appropriate to consider a provision of 21 U.S.C. 824(a) when determining whether to grant a practitioner registration application. For over forty-five years, Agency decisions have concluded that it is. *Robert Wayne Locklear, M.D.*, 86 FR 33738, 33744–45 (2021) (collecting cases); *see also Dinorah Drug Store, Inc.*, 61 FR 15972, 15973–74 (1996).

³ Based on the Government's submissions in its RFAA dated July 3, 2023, the Agency finds that service of the OSC on Applicant was adequate. Specifically, the included Declaration of a DEA Diversion Investigator indicates that on January 30, 2023, Applicant was personally served with the OSC. RFAAX 1, at 2.

⁴ Within the document where Applicant withdrew his request for hearing, Applicant's counsel indicated that Applicant would “continue with the Corrective Action Plan route that was parallel to the litigation path, but unrelated to the hearing.” *Id.* at 1.

⁵ *See also* 21 CFR 1301.43(f)(3) (“A party held to be in default may move to set aside a default final order issued by the Administrator by filing a motion no later than 30 days from the day of issuance by the Administrator of a default final order. Any such motion shall be granted only upon a showing of good cause to excuse the default.”) Any motion to set aside a default and any response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at dea.addo.attorneys@dea.gov.

manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1).

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enf't Admin.*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993).

While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1),⁶ the Government's evidence in support of its *prima facie* case for denial of Applicant's application for registration is confined to Factors B and D. See RFAAX 1, Attachment E, at 1. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44. Here, the Agency finds that the Government's evidence satisfies its *prima facie* burden of showing that Applicant's registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4).

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. See *Sualeh Ashraf, M.D.*, 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022). In the current matter, the Government has alleged that Applicant violated both Federal and State law regulating

controlled substances. RFAAX 1, Attachment E, at 2.⁷ Specifically, Federal law states that "[a] prescription for a controlled substance may be issued only by an individual practitioner who is: (1) [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and (2) [e]ither registered or exempted from registration pursuant to §§ 1301.22(c) and 1301.23" 21 CFR 1306.03(a)(1)–(2). As for State law, Virginia statute requires that "[e]very person who manufactures, distributes or dispenses any substance that is controlled in [s]chedules I through V . . . except . . . those persons who are licensed practitioners of medicine . . . shall obtain annually a controlled substances registration certificate issued by the [Board of Pharmacy]. This registration shall be in addition to other licensing or permitting requirements enumerated in [Virginia's Drug Control Act] or otherwise required by law." Va. Code Ann. section 54.1–3422(A).

Here, Applicant has admitted that he repeatedly issued prescriptions for controlled substances while his DEA registration was suspended as well as after his DEA registration was revoked. As such, the Agency finds that Applicant violated 21 CFR 1306.03(a)(1)–(2) and Virginia Code section 54.1–3422(A).

Accordingly, the Agency finds that Factors B and D weigh in favor of denial of Applicant's application and thus finds Applicant's continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). The Agency further finds that Applicant failed to provide any evidence to rebut the Government's *prima facie* case.

III. Sanction

Where, as here, the Government has established grounds to deny Applicant's application, the burden shifts to the registrant to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18882, 18910 (2018). To establish that he can be entrusted with registration, a registrant must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195*, 77 FR 62316, 62339 (2012) (internal quotations omitted); see also *Michele L. Martinho, M.D.*, 86 FR 24012, 24019 (2021); *George D. Gowder, III, M.D.*, 89 FR 76152,

76154 (2024). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. See, e.g., *Robert Wayne Locklear, M.D.*, 86 FR at 33746.

Here, although Applicant initially requested a hearing, he ultimately withdrew his hearing request and did not otherwise avail himself of the opportunity to refute the Government's case. As such, Applicant has made no representations as to his future compliance with the CSA nor demonstrated that he can be entrusted with registration. Moreover, the evidence presented by the Government shows that Applicant violated the CSA, further indicating that Applicant cannot be entrusted. Accordingly, the Agency will order the denial of Applicant's application.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1) and 21 U.S.C. 824(a), I hereby deny the pending application for a Certificate of Registration, Control No. W22109452C, submitted by Salman Akbar, M.D., as well as any other pending application of Salman Akbar, M.D., for additional registration in Virginia. This Order is effective November 12, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 4, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–23504 Filed 10–9–24; 8:45 am]

BILLING CODE 4410–09–P

⁶ As to Factor A, the record contains no evidence of a recommendation from any State licensing board or professional disciplinary authority. 21 U.S.C. 823(g)(1)(A). Nonetheless, an absence of such evidence "does not weigh for or against a determination as to whether continuation of [or granting of a] DEA certification is consistent with the public interest." *Roni Dreszer, M.D.*, 76 FR 19434, 19444 (2011). As to Factor C, there is no evidence in the record that Applicant has been convicted of an offense under either Federal or State law "relating to the manufacture, distribution, or dispensing of controlled substances." 21 U.S.C. 823(g)(1)(C). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor. *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010). Agency cases have therefore found that "the absence of such a conviction is of considerably less consequence in the public interest inquiry" and is therefore not dispositive. *Id.* Finally, as to Factor E, the Government's evidence fits squarely within the parameters of Factors B and D and does not raise "other conduct which may threaten the public health and safety." 21 U.S.C. 823(g)(1)(E). Accordingly, Factor E does not weigh for or against Applicant.

⁷ The Agency need not adjudicate the criminal violations alleged in the instant OSC. *Ruan v. United States*, 142 S. Ct. 2370 (2022) (decided in the context of criminal proceedings).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 23–22]

Midtown Specialty RX; Decision and Order

On January 25, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Midtown Specialty RX (Respondent) of Houston, Texas. OSC/ISO, at 1. The OSC/ISO informed Respondent of the immediate suspension of its DEA Certificate of Registration, Control No. FM2396427, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes “an imminent danger to the public health or safety.” *Id.* (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Respondent's registration, alleging that Respondent's continued registration is inconsistent with the public interest because, among other reasons, Respondent repeatedly dispensed controlled substance prescriptions to over sixty patients without resolving red flags of drug abuse and diversion. *Id.* (citing 21 U.S.C. 823(g)(1),¹ 824(a)(4)).

A hearing was held before DEA Administrative Law Judge Paul E. Soeffing (the ALJ) who, on July 13, 2023, issued his Recommended Findings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), which recommended revocation of Respondent's registration. RD, at 67. Respondent did not file exceptions to the RD. Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings,² credibility findings,³

findings of fact, conclusions of law, sanctions analysis, and recommended sanction as found in the RD and summarizes and expands upon portions thereof herein.

I. Findings of Fact

Standard of Care—Dispensing

Katherine Salinas, R.Ph., who is currently employed full-time as a Compliance Officer for the Texas State Board of Pharmacy, credibly testified for the Government as an expert in the standard of care and the professional responsibility required of a Texas pharmacy in its dispensing practices. RD, at 7–8, 21; Tr. 128, 131, 133–134; Government Exhibit (GX) 4, at 8.⁴ According to Ms. Salinas, prior to dispensing a prescription for a controlled substance, Texas pharmacists are required to determine whether the prescription was issued in the usual course of professional practice and to make every reasonable effort to ensure that the prescription was issued for a legitimate medical purpose. RD, at 8, 9; Tr. 134, 135. Further, in making that determination, Texas pharmacists are required to exercise sound professional judgment, meaning that they must evaluate the prescription in its entirety and must contact the prescriber if the authenticity of the prescription is in question. RD, at 8–9; Tr. 134–135.

Ms. Salinas's testimony is consistent with Texas law which states that “[a] pharmacist may not . . . dispense or deliver a controlled substance . . . except under a valid prescription and in the course of professional practice.” Tex. Health & Safety Code section 481.074(a)(1). Texas law notes that “[a] pharmacist may not . . . dispense a controlled substance if the pharmacist knows or should have known that the prescription was issued without a valid patient-practitioner relationship.” *Id.*

but ultimately gave her testimony less weight than he otherwise would have due to her prior interactions with Respondent during the course of her duties as a Compliance Officer. *Id.* at 21–22. Regarding the Respondent's case, the Agency agrees with the ALJ that the testimony from Respondent's former pharmacist-in-charge, E.W., which was focused on describing her process for filling prescriptions at Respondent, was generally credible and internally consistent, though, as noted by the ALJ, E.W.'s testimony was not specific to the prescriptions at issue and minimal evidence was offered in corroboration. *Id.* at 23. Finally, the Agency agrees with the ALJ that the testimony from Respondent's owner, S.M., which addressed Respondent's procedures for filling prescriptions, addressing red flags, keeping inventories, and securing controlled substances, was generally credible; however, minimal evidence was offered to corroborate her testimony and, as the ALJ noted, S.M. has a significant personal interest in the outcome of the proceedings. *Id.* at 28.

⁴ For Ms. Salinas's full qualifications, see GX 43; RD, at 7–8.

section 481.074(a)(2). Texas regulations require that a Texas pharmacist “shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order” and “shall make every reasonable effort to ensure that any prescription drug order . . . has been issued for a legitimate medical purpose by a practitioner in the course of medical practice.” 22 Tex. Admin. Code sections 291.29(a)–(b), 291.34(b)(1).

Ms. Salinas also testified that Texas pharmacists must check the Prescription Drug Monitoring Program (PDMP) and must attempt to resolve and document the resolution of any “red flags”—warning signs or problematic patterns that indicate a potential for diversion—prior to dispensing controlled substances. RD, at 9–10; Tr. 135–136, 270.

In discussing red flags, Ms. Salinas testified that some of the known red flags include: the same doctor or group of doctors repeatedly prescribing the same strength and dosage of medication over a long period of time and/or for multiple patients (also called “pattern prescribing”); prescriptions from a small group of doctors; patients traveling long distances to the pharmacy; multiple patients sharing the same address and receiving prescriptions for the same controlled substances from the same prescribers;⁵ and “non-therapeutic prescribing and dispensing” where controlled substances are illegitimately prescribed or dispensed with other controlled and/or noncontrolled (including over-the-counter) substances.⁶ RD, at 9, 10, 11, 14, 19; Tr. 136, 144, 146, 147, 159–160, 171, 173–174, 233–234, 281. Ms. Salinas testified that one red flag is sufficient to “raise concern” and that pharmacists have an ongoing responsibility to resolve red

⁵ Ms. Salinas clarified that prescriptions issued within a month or two of each other that list the same address for the same controlled substance and written by the same prescriber would create a shared address red flag, whereas prescriptions issued and filled at a longer period apart with those same characteristics may not be caught or noticed by a pharmacist; a red flag determination would be “diminished” beyond the one-month timeframe. RD, at 11; Tr. 277–278.

⁶ Ms. Salinas testified that receiving prescriptions for two opioids is uncommon and indicative of potential diversion; illegitimate prescriptions for schedule II controlled substances are commonly prescribed with other controlled and noncontrolled substances to give the illusion of legitimacy. RD, at 19; Tr. 233–234, 236. According to Ms. Salinas, the Texas State Board of Pharmacy rules and regulations warn pharmacists that a 1:1 ratio of controlled substances to noncontrolled or over-the-counter substances could indicate nontherapeutic dispensing and diversion. RD, at 19; Tr. 235. Ms. Salinas noted that these kinds of prescriptions are also referred to as “cocktail” or “cocktail-like” prescriptions. RD, at 19; Tr. 237.

¹ Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC/ISO, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

² The only exception is with regards to allegations concerning the cash payment red flag, which this Decision and Order does not address due to the number and egregiousness of the rest of the allegations.

³ The Agency adopts the ALJ's summary of each of the witnesses' testimonies as well as the ALJ's assessment of each of the witnesses' credibility. See RD, at 4–28. The Agency agrees with the ALJ that the testimony from the Government's expert witness, Ms. Katherine Salinas, R.Ph., which was focused on the Texas standard of care and Respondent's dispensing to the patients listed in the OSC/ISO, was credible in that it was internally consistent, logically persuasive, and presented an objective analysis. RD, at 21. The ALJ found that Ms. Salinas's testimony was credible and reliable,

flags—even if they are resolving the same red flags repeatedly—and to document their resolution. RD, at 9; Tr. 137–138, 143. Ms. Salinas also stated that if a pharmacist is unable to resolve a red flag, then he or she should not dispense the prescription. RD, at 9; Tr. 137, 247–248.

Similarly, the Texas Board of Pharmacy sets forth numerous operational standards for pharmacists filling prescriptions, requiring, firstly, that “[f]or the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient’s medication record. Such review shall at a minimum identify clinically significant . . . (III) reasonable dose and route of administration; . . . (VI) drug-drug interactions; . . . and (X) proper utilization, including overutilization or underutilization.” *Id.* section 291.33(c)(2)(A)(i). Further, “[u]pon identifying any clinically significant conditions . . . the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner.” *Id.* section 291.33(c)(2)(A)(ii).

A Texas pharmacist must ensure that “[p]rior to dispensing, any questions regarding a prescription drug order [] be resolved with the prescriber and written documentation of these discussions [be] made and maintained.” *Id.* section 291.33(c)(2)(A)(iv). Such documentation must be made “on the prescription or in the pharmacy’s data processing system associated with the prescription . . . and shall include . . . (i) [the] date the prescriber was consulted; (ii) [the] name of the person communicating the prescriber’s instructions; (iii) any applicable information pertaining to the consultation; and (iv) [the] initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.” *Id.* section 291.33(c)(2)(C).

Finally, a Texas pharmacist must consider the various “red flag factors” in “preventing the non-therapeutic dispensing of controlled substances,” including, among others: pattern prescribing; prescriptions for controlled substances commonly known to be abused; prescriptions for controlled substances at the highest strength and/or in large quantities, indicating lack of individual drug therapy; multiple patients sharing the same address and obtaining similar controlled substance prescriptions from the same practitioner; and patients consistently

paying for controlled substance prescriptions with cash rather than through insurance. *Id.* section 291.29(f).

Respondent’s Inappropriate Dispensing Pattern Prescribing

In reviewing the relevant PDMP data and patient profiles in the current matter, Ms. Salinas identified numerous instances and types of pattern prescribing. RD, at 10; Tr. 144–145. Specifically, Ms. Salinas noted that Respondent’s most frequently dispensed controlled substances were oxycodone,⁷ hydrocodone,⁸ and promethazine with codeine.⁹ RD, at 10; Tr. 144–145. Ms. Salinas explained that the opioids oxycodone and hydrocodone, the muscle relaxant carisoprodol, and promethazine cough syrup with codeine generate greater concern for diversion in instances of potential pattern prescribing because these drugs are commonly abused and diverted in the Houston area. RD, at 10–11; Tr. 141–142. Ms. Salinas also noted that prescriptions for “strong opioids” were written for and dispensed in “at least” a month’s supply (over 100 tablets).¹⁰ RD, at 10, 46; Tr. 144–145. Further, Ms. Salinas testified that 80 percent of the oxycodone prescriptions were written by the same three physicians, with a majority of these written by the same single physician, Dr. L.S.¹¹ RD, at 10; Tr. 144–145. Ms. Salinas testified that she reviewed the patient profiles, physician profiles, and the numerous prescriptions for oxycodone 30 mg, hydrocodone-acetaminophen 10–325 mg, and promethazine with codeine, and found no notations resolving any of the red flags, let alone the pattern prescribing red flag. RD, at 46; Tr. 147–230.

Moreover, Ms. Salinas testified regarding several examples of Respondent’s dispensing that suggested a lack of individualization, another indicator of the pattern prescribing red flag. RD, at 47–48. For example, Patient M.B. always received a prescription for oxycodone along with a rotation of noncontrolled and over-the-counter substances such as a stool softener, ibuprofen, a muscle relaxant, vitamin D,

and folic acid; meanwhile, Patient W.J. received prescriptions of oxycodone paired with a 300-day supply¹² of stool softener, which Ms. Salinas opined was particularly odd based on the number of tablets prescribed. RD, at 47; Tr. 234–239; *see also* GX 28, at 2, 7–8; GX 30, at 2–20.

In Ms. Salinas’s un rebutted expert opinion, the red flag of pattern prescribing present in these prescriptions needed to be resolved before they were dispensed and such resolution needed to be documented; because there was no documented resolution of these red flags, Ms. Salinas found that Respondent failed to meet its corresponding responsibility. RD, at 11, 48; Tr. 146–147, 234, 239, 241–242. As such, the Agency agrees with the ALJ and finds that Respondent dispensed controlled substance prescriptions that presented the red flag of pattern prescribing and failed to properly document and resolve this red flag prior to dispensing; accordingly, Respondent filled these controlled substance prescriptions outside the usual course of professional practice in violation of the Texas standard of care. RD, at 49.

Shared Addresses

One of Texas’ red flag factors is “multiple persons with the same address present[ing] substantially similar controlled substance prescriptions from the same practitioner.” 22 Tex. Admin. Code section 291.29(f)(11). Regarding the issue of shared addresses, Ms. Salinas provided many examples of Respondent’s dispensing that raised the shared address red flag. RD, at 51–52. For example, Patients J.J. and S.B., who share an address, were both prescribed oxycodone 30 mg from Dr. L.S.; Respondent dispensed these prescriptions on January 6, 2022, and January 7, 2022, respectively. RD, at 51–52 n. 89; GX 44, at 20.¹³ Dr. L.S. also issued prescriptions for 30 mg of oxycodone, all of which Respondent dispensed, to all of the following groups of patients with shared addresses: (1) G.V. on March 2, 2022, J.L. on March 10, 2022, and B.G. on April 21, 2022; (2) K.M. on August 4, 2021, and M.B. on August 20, 2021; (3) D.O. on August 18, 2021, and C.P. on August 19, 2021; and (4) C.B. and L.N. both on December 22, 2021. RD, at 52 n. 90, 92–95. Moreover, Respondent dispensed substantially

⁷ *See* Tr. 148–159, 163–170, 195, 201–203, 219–220; GX 19, 26–28, 44 (Patients E.D., R.H., B.Y., D.S., J.J., S.B., G.V., J.L., B.G., D.G., B.J., K.M., M.B., D.O., C.P., T.P., Y.Y., C.B., L.N., B.B., D.P., J.C., M.H., L.M., R.T., T.M., D.A., R.P., S.S., T.C., C.H., E.H., L.S., R.J., W.J., and R.B.).

⁸ *See* Tr. 170–171, 207; GX 31, 44 (Patients V.R., H.L., T.H., and B.B.).

⁹ *See* Tr. 199; GX 22. (Patient J.A.).

¹⁰ *See* Tr. 235–236; GX 31 (Patient B.B.).

¹¹ *See* Tr. 148–159; GX 44 (Patients E.D., R.H., B.Y., D.S., J.J., S.B., G.V., J.L., B.G., D.G., B.J., K.M., M.B., D.O., C.P., T.P., Y.Y., C.B., and L.N.).

¹² Without a documented explanation, Respondent filled only 100 of the tablets. RD, at 47 n. 84; Tr. 238–239.

¹³ *See also* Tr. 148–159; GX 44 (Patients E.D., and B.Y.; Patients J.J. and S.B.; Patients G.V., J.L., and B.G.; Patients K.M. and M.B.; Patients D.O. and C.P.; and Patients C.B. and L.N.).

similar prescriptions for oxycodone 30 mg and other opioids issued by Drs. D.A., W.K., B.R., and M.Q. that were also prescribed to patients who shared the same address.¹⁴ RD, at 12–13; Tr. 147–172; GX 44.

In Ms. Salinas's credible and un rebutted expert opinion, the red flag of shared addresses present in these prescriptions needed to be resolved before they were dispensed and such resolution needed to be documented; because there was no documented resolution of this red flag, Ms. Salinas found that Respondent failed to meet its corresponding responsibility. RD, at 14, 53; Tr. 162, 171–72, 279–280. As such, the Agency agrees with the ALJ and finds that Respondent dispensed controlled substances, issued less than two months apart, to patients who shared addresses and received prescriptions for the same controlled substances from the same prescriber. RD, at 54. Moreover, Respondent failed to properly resolve and document resolution of the shared address red flag prior to dispensing and, accordingly, filled these controlled substance prescriptions outside the usual course of professional practice in violation of the Texas standard of care. *Id.*

Long Distances

One of Texas' red flag factors is "the geographical distance between the practitioner and the patient or between the pharmacy and the patient." 22 Tex. Admin. Code section 291.29(c)(4) (emphasis added). Ms. Salinas testified that Houston pharmacies generally use 30 miles as a guideline for when a distance traveled by a patient becomes a red flag. RD, at 16–17; Tr. 214. Ms. Salinas noted that the long-distance red flag can be resolved, but a pharmacist should have a conversation with the patient, document the specific issue or concern on the prescription, and document any reasonable explanation that resolves the red flag before dispensing the prescription. RD, at 17; Tr. 212–213, 229–230.

Regarding the red flag of long distances, Ms. Salinas testified that she calculated the distances traveled in the current matter based on the home addresses listed on the patients' prescriptions filled at Respondent. RD, at 18; Tr. 216–218. Based on her calculations, Ms. Salinas found that multiple patients traveled far beyond the guideline of 30 miles of their home addresses to fill prescriptions at

Respondent.¹⁵ For example, the following patients all traveled the following miles one way to fill prescriptions for oxycodone 30 mg at Respondent: E.H., 84.1 miles one way (Tr. 215–218); R.J., 92.5 miles one way (Tr. 220–221); R.B., 88.5 miles one way (Tr. 219–220); L.S., 74 miles one way (Tr. 222–223); W.J., 79.5 miles one way (Tr. 223–224); J.A., 167.5 miles one way (Tr. 224–225). RD, at 56–57. Ms. Salinas further testified that there was no documentation providing alternate addresses, distances, or explanations that documented a resolution of these red flags. RD, at 18, 57; Tr. 216–218, 225–229.

In Ms. Salinas's un rebutted expert opinion, the red flag of long distances present in these prescriptions needed to be resolved before they were dispensed and such resolution needed to be documented; because there was no documented resolution of this red flag, Ms. Salinas found that Respondent failed to meet its corresponding responsibility. RD, at 17, 20. Tr. 212–213, 241–242. As such, the Agency agrees with the ALJ and finds that Respondent dispensed controlled substances to patients who traveled long distances and failed to properly resolve and document resolution of the long-distance red flag prior to dispensing; accordingly, Respondent filled these controlled substance prescriptions outside the usual course of professional practice and in violation of the Texas standard of care. RD, at 59.

Respondent's Arguments Regarding Inappropriate Dispensing

Regarding Respondent's case, E.W. was the pharmacist-in-charge at Respondent at the time of the relevant events. RD, at 22; Tr. 304, 307. E.W. testified credibly, but with little corroborating evidence, regarding Respondent's general dispensing practices; however, she did not testify specifically regarding the prescriptions at issue in this case. RD, at 23. With regard to Respondent's general practice, E.W. testified that before dispensing prescriptions, she would get a phone number from the patient, discuss insurance with the patient, and then make a copy of the patient's driver's license. RD, at 22; Tr. 304. Next, after reviewing the full PDMP drug history of the patient, if "everything check[ed] out," E.W. would enter the prescription, pull the medication, and "go through the process." RD, at 22; Tr. 304–305. E.W. explained that she would check to

make sure that prescribers were "proper by law" and Houston-based, adding that the pharmacy only filled prescriptions from Houston doctors "in good standing." ¹⁶ RD, at 22; Tr. 305–307. E.W. testified that she never documented what she discovered through the verification process. RD, at 22 n.58, 23; Tr. 308, 310. Then, E.W. would fill the prescription, counsel the patient, and have him or her sign documentation affirming that he or she had been counseled. RD, at 22; Tr. 305. E.W. noted that the pharmacy has refused to fill prescriptions in the past, but admitted that she would not document her concerns or reasons for refusing to fill the prescription. RD, at 22–23; Tr. 308, 310–311. Again, E.W. did not testify specifically regarding the procedures followed with regard to the prescriptions at issue, but she did acknowledge that she knew that the PDMP data would have indicated that the same group of doctors was prescribing the same strength and quantity of medication to multiple patients. RD, at 22–23; Tr. 310.

As for Respondent's owner, S.M., she testified that though she is not a licensed pharmacist, she works as a pharmacy technician at Respondent. RD, at 23; Tr. 313–314. S.M.'s testimony was generally credible, but there was little corroborating evidence and the ALJ noted that she has a significant personal interest in the outcome of the proceedings. RD, at 28. S.M. testified generally regarding Respondent's process, stating that the pharmacy only fills prescriptions written by doctors in the Houston area. RD, at 23; Tr. 315. When asked whether Respondent "check[ed] to make sure the prescriptions were legitimate," S.M. testified that Respondent "hired a third party to go out to the doctors' offices to verify the doctors, check their licenses, [and] check to make sure that they were abiding by the red flag checklist." ¹⁷ Tr. 318; *see also* RD, at 23–24; Tr. 315–316, 321.¹⁸ S.M. testified that when a patient

¹⁶ E.W. testified that to verify "good standing" "offices were called[,] . . . someone went out to check the doctors," or she would check the Texas Medical Board's website. RD, at 22 n.58, 23; Tr. 308, 310.

¹⁷ The Agency notes that pharmacies have a "corresponding responsibility" to ensure proper dispensing of controlled substances that exists independent of a prescriber's responsibility. 21 CFR 1306.04(a). Nothing in Ms. Salinas's testimony suggests that making sure that prescribers are abiding by the red flag checklist is part of a pharmacy's corresponding responsibility. *See supra* Standard of Care—Dispensing.

¹⁸ As evidence that Respondent generally took steps to identify red flags prior to dispensing, S.M. testified that she had sent at least one letter to the Texas Medical Board reporting physicians who

¹⁴ *See* Tr. 163–171; GX 44 (Patients B.B. and D.P.; Patients L.M. and R.T.; Patients T.C. and R.P.; Patients H.L. and T.H.).

¹⁵ *See* Tr. 215–225; RD, at 3–4, Stip. 12–17; GX 19, 22, 24, 26–28 (Patients E.H., R.B., R.J., L.S., W.J., and J.A.).

entered the pharmacy, either a pharmacist or herself would ask the patient for identification, take down the patient's allergy information and phone number, check the PDMP for "anything that might stand out," and "verify" the prescription with the prescriber by calling the prescriber. RD, at 24; Tr. 330–331.¹⁹ S.M. testified that if "everything check[ed] out," Respondent would fill the prescription, at which time the pharmacist would "counsel the patient about [the] medication" and answer any questions. RD, at 24; Tr. 331.²⁰

Regarding Respondent's procedure for addressing and resolving red flags, S.M. agreed that Texas pharmacies are to determine the legitimacy of prescriptions by resolving red flags and that resolution of red flags must be properly documented. RD, at 25; Tr. 370. S.M. testified that Respondent would "check the patient, contact the doctor, verify the prescription[,] . . . [and] verify any information that [it] could from the patient." RD, at 24; Tr. 321. S.M. also testified that Respondent has refused to fill prescriptions in the past if, upon review of PDMP data, the pharmacist found that the patient was presenting for an early refill, the prescription was fraudulent, or the pharmacist did not think the prescription was legitimate. RD, at 24–25; Tr. 314. S.M. testified that if the pharmacist refuses to fill a prescription, the pharmacy keeps no record of that refusal and shreds the unfilled prescription; S.M. also asserted that "[the pharmacy does not] have to document that [it] didn't fill the prescription." RD, at 25; Tr. 314–315.

were writing questionable prescriptions. RD, at 24 n.60; Tr. 318–20; Respondent Exhibit (RX) 7, at 1–2. Even so, there is no evidence that respondent identified and resolved the relevant red flags prior to dispensing the controlled substances at issue in this case.

¹⁹ S.M. agreed that PDMP data would show information pertaining to prescribers who write prescriptions for oxycodone 30 mg to multiple patients for multiple months. RD, at 25; Tr. 361–362.

²⁰ S.M. testified that if Respondent needed information on a patient's diagnosis or condition or any other additional information, someone working at Respondent would call the prescriber, who "would let [Respondent] know at length about [the patient's] medical records, if [the patient was] in an accident or if [the patient] had some kind of other ailment going on," whoever called the prescriber would document the information by "[writing] it down sometimes in the patient's profile and sometimes on the back of the prescription." RD, at 24; Tr. 328. S.M. testified that on the back of prescriptions, she would note "if something changed with the prescription, if the quantity was incorrect or the doctor wrote the SIG wrong, things like that." RD, at 24; Tr. 329. However, there is no evidence of such documentation for the relevant prescriptions.

S.M. testified that "patient counseled" written on prescriptions²¹ reflects that the prescription was "resolved to the pharmacist's satisfaction" through the steps that S.M. testified Respondent takes prior to dispensing. RD, at 25; Tr. 363, 365. Notably, E.W. testified that she had written "consult," not "patient counseled," on the prescriptions at issue in this case to indicate that she had looked at the PDMP. RD, at 22; Tr. 306, 363. However, review of the prescription records at issue indicates that only "counseled" or "patient counsel" (and not "consult") were ever written on the prescriptions at issue, and review of both E.W. and S.M.'s full testimony suggests there is no distinction between the use of the words "consult" and "counsel." This suggests an imprecise word choice by E.W. All that is relevant to this matter is that the prescriptions said "counseled" or "patient counsel" and S.M. testified that more detailed patient notes were unnecessary because Respondent conducts the same process for all patients and all prescriptions, including refill prescriptions. RD, at 25; Tr. 363–364.

Contrary to S.M.'s testimony, Ms. Salinas opined that the handwritten note to the effect of "patient counsel" present on the majority of the prescriptions at issue in the current matter does not constitute red flag resolution. First, she testified, patient counseling is a separate requirement under the Texas State Board of Pharmacy regulations, and "counseling usually entails talking about what the medication is, how to take it, what to do if you miss a dose, side effects to watch out for . . . that sort of thing." RD, at 16, 18; Tr. 187–188, 209–210, 229–230. Second, even if Respondent writing "patient counsel" was meant to show red flag resolution, the notations in the current matter do not satisfy the requirement of documentation of red flag resolution because they "[do not] tell the story." RD, at 16, 18; Tr. 187–188, 209–210, 229–230. The Agency credits Ms. Salinas's expert opinion that Respondent failed to adequately document resolution of the relevant red flags prior to dispensing each of the prescriptions at issue in this case. See *supra*, at Respondent's Inappropriate Dispensing; see also RD, at 28.

²¹ When S.M. was first asked what "counseled patient" written on the back of a prescription meant, she testified that that it meant that the pharmacist had counseled the patient "at length about [the] prescription." Tr. 329. This testimony is consistent with Ms. Salinas's testimony regarding the typical meaning of the notation. See *infra*; RD, at 16; Tr. 187–88; 209–10.

Regarding the various red flags at issue in the current matter, S.M. testified that the patients who traveled to Respondent from non-Houston addresses did so because the pharmacies near their homes do not carry controlled substances prescribed to treat pain. RD, at 26; Tr. 325.²² Respondent did not present evidence to support this claim nor evidence that this information was documented in either patient profiles or on patients' prescriptions.²³

Standard of Care—Inventory, Recordkeeping, and Storage

The CSA requires pharmacies to keep accurate and timely records of inventory and dispensing, including initial and biennial inventories. 21 CFR 1304.11(a)–(c). Texas law also requires pharmacies to keep and maintain records, including "a perpetual inventory of any controlled substance listed in Schedule II." 22 Tex. Admin. Code section 291.75(a)(1), (c)(4)–(5).

Ms. Salinas testified that Texas pharmacies are required to keep and maintain accurate records of all prescriptions, invoices, signature logs for individuals participating in prescription processing, counseling documentation, and controlled substance inventories for at least two years. RD, at 10, 60; Tr. 138–139. Ms. Salinas also testified that Texas pharmacies are required by law to have inventories of all controlled substances available for inspection. RD, at 20–21; Tr. 243. Ms. Salinas noted that under the Texas standard of care, in the case of a disaster such as a flood, a pharmacy must notify the Texas State Board of Pharmacy within ten days and should immediately re-conduct an inventory. RD, at 21; Tr. 243–244.

The CSA requires that "[c]ontrolled substances listed in Schedules II, III, IV, and V . . . be stored in a securely locked, substantially constructed cabinet." 21 CFR 1301.75(b); RD, at 60. Regarding storage, Ms. Salinas testified that Texas pharmacies must keep their controlled substances stored, locked, and secured at their registered location as well as have written security policies and procedures, motion sensors, and an alarm system with offsite monitoring. RD, at 10, 21, 61; Tr. 139, 245. Ms. Salinas testified that she was not aware

²² S.M. testified that Respondent was "never instructed to write . . . if the patient's address was far away" and that "[Respondent has] been inspected several times by Ms. Salinas, and . . . [has] never been directed by her to do that." RD, at 25; Tr. 364. Even if true, this does not relieve Respondent of its obligations under Texas law.

²³ See, e.g., *George Pursley, M.D.*, 85 FR 80162, 80171 n.28 (2020) ("Post hoc written or oral justifications . . . are not controlling.").

of any exceptions to these requirements and that it would be concerning to her if a registrant was storing controlled substances at a personal residence; further, Ms. Salinas opined that there is no justification for removing controlled substances from the registered location and if drugs are ever moved, registrants are required to document the move. RD, at 21; Tr. 245–246.

Respondent's Case

S.M. admitted that Respondent did not have initial, ending, or biennial inventories at the time of DEA's June 1, 2022 inspection and that the last annual inventory that Respondent had on file was for 2020. RD, at 26, 60; Tr. 339, 344, 352–353. S.M. testified that in late 2021, a pipe burst in a neighboring business causing a flood that damaged Respondent's inventories. RD, at 26; Tr. 340–341, 344, 351. S.M. admitted that she "should have immediately recreated" the inventory and that not doing so was a mistake in judgment. RD, at 26–27; Tr. 348–349. S.M. testified that she has since taken remedial action by updating Respondent's perpetual inventory on a daily basis. RD, at 27; Tr. 349. S.M. acknowledged that Respondent's current inventory was initially generated on June 1, 2022, during the DEA inspection when Respondent's pharmacist-in-charge and DEA Diversion Investigators conducted a pill count upon return of the controlled substances from S.M.'s residence to Respondent's registered location. RD, at 27; Tr. 353. S.M. also acknowledged that at least six months had passed between the date that she asserts Respondent's inventories were damaged by flooding and the June 1, 2022 inspection, with S.M. testifying that she tried to recreate the inventory during that time but that it "takes a lot to recreate an inventory." RD, at 27; Tr. 353–354. S.M. asserted that Respondent has since corrected the situation and that on the date that the OSC/ISO was issued in the current matter, Respondent had current inventories. RD, at 26; Tr. 345.

S.M. also admitted that without permission from DEA or the Texas State Board of Pharmacy, she removed controlled substances from Respondent's registered location and transported them to her personal residence on a daily basis. RD, at 27, 61; Tr. 111, 338. S.M. acknowledged that while she was transporting drugs to and from her home, there was a working safe at the pharmacy. RD, at 28; Tr. 360.²⁴

S.M. testified that she took the controlled substances home "to ensure the safety of the drugs" after there were burglaries and robberies in the neighborhood where Respondent is located, including two instances of attempted burglary at Respondent itself. RD, at 27, 61; Tr. 336–338, 355–358; RX 4–5.²⁵ S.M. also testified that she removed the controlled substances from Respondent because "[w]hen the pandemic started, it was chaos[,] . . . [there was] no clear direction on what to do with anything[,] . . . [e]verybody was working from home . . . [and] [n]obody knew what to do . . . [because] [nobody could] get in contact with anyone." RD, at 27–28; Tr. 338–339. S.M. testified that she has since taken remedial action by keeping Respondent's controlled substances locked in the safe at the registered location and she has stopped transporting controlled substances to and from Respondent on a daily basis following the June 2022 inspection. RD, at 28; Tr. 349, 338–339.

Based on Respondent's admissions, the Agency agrees with the ALJ that Respondent did not take and/or keep initial or biennial inventories as of the date of DEA's June 2022 inspection and did not store its controlled substances in a securely locked and substantially constructed cabinet. RD, at 60, 61; ALJ Exhibit 7 (Respondent's Answer), at 2.

II. Discussion

A. The Five Public Interest Factors

Under the CSA, "[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

being kept in an unlocked suitcase in the closet. RD, at 61; Tr. 41–45; GX 41, at 1–2.

²⁵ S.M. testified that she had called both DEA and the Texas State Board of Pharmacy regarding the attempted burglaries but that neither entity "did anything." RD, at 27 n.63; Tr. 338. S.M. testified that "[she] thought [she] was doing the correct thing by taking the drugs and taking them away from an environment where [people] were breaking in and trying to rob[.]" . . . [b]ut [she] [does] know now that [she] was not doing the right thing, and [she] would not do it again." RD, at 28; Tr. 348.

(C) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1).

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enft Admin.*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1), the Government's evidence in support of its *prima facie* case for revocation of Respondent's registration is confined to Factors B and D. RD, at 31–32; *see also id.* at 31 n.66 (finding that Factors A, C, and E do not weigh for or against revocation).

Having reviewed the record and the RD, the Agency agrees with the ALJ, adopts the ALJ's analysis, and finds that the Government's evidence satisfies its *prima facie* burden of showing that Respondent's continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4); RD, at 31–62.

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See Sualeh Ashraf, M.D.*, 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022). In the current matter, the Government has alleged that Respondent violated numerous Federal and State laws regulating controlled substances. OSC/ISO, at 2–10.²⁶ Specifically, Federal law requires that "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice," and that "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a), 1306.06;

²⁶ The Agency need not adjudicate the criminal violations alleged in the instant OSC/ISO. *Ruan v. United States*, 142 S. Ct. 2,370 (2022) (decided in the context of criminal proceedings).

²⁴ A DEA Diversion Investigator testified that during the June 2022 inspection, she retrieved controlled substances from S.M.'s home that were

see also 21 U.S.C. 829. Federal law also emphasizes that although “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription.” 21 CFR 1306.04(a).²⁷ Regarding recordkeeping, inventory, and storage, Federal law requires that “[c]ontrolled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet.” *Id.* § 1301.75(b). In addition, pharmacies are required to keep and maintain accurate and timely records of dispensing and inventory, including initial and biennial inventories. *Id.* § 1304.11(a)–(c).²⁸

As for State law, Texas regulations require that “[a] pharmacist may not . . . dispense or deliver a controlled substance . . . except under a valid prescription and in the course of professional practice.” Tex. Health & Safety Code section 481.074(a)(1).²⁹ The Texas Board of Pharmacy also sets forth numerous operational standards for pharmacists filling prescriptions, requiring, firstly, that pharmacists “shall, prior to or at the time of dispensing a prescription drug order, review the patient’s medication record. Such review shall at a minimum identify clinically significant . . . (III) reasonable dose and route of administration; . . . (VI) drug-drug interactions; . . . and (X) proper utilization, including overutilization or

underutilization.” *Id.* section 291.33(c)(2)(A)(i). Further, “[u]pon identifying any clinically significant conditions . . . the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner.” *Id.* section 291.33(c)(2)(A)(ii). A Texas pharmacist must also ensure that “[p]rior to dispensing, any questions regarding a prescription drug order [] be resolved with the prescriber and written documentation of these discussions [be] made and maintained.” *Id.* section 291.33(c)(2)(A)(iv).³⁰ Finally, a Texas pharmacist must consider the various “red flag factors” in preventing the non-therapeutic dispensing of controlled substances, including, among others: pattern prescribing; prescriptions for controlled substances commonly known to be abused; prescriptions for controlled substances at the highest strength and/or in large quantities, indicating lack of individual drug therapy; multiple patients sharing the same address and obtaining similar controlled substance prescriptions from the same practitioner; and patients consistently paying for controlled substance prescriptions with cash rather than through insurance. *Id.* section 291.29(f). “The geographical distance between the practitioner and the patient or between the pharmacy and the patient,” can present as an additional red flag factor under Texas regulations. 22 Tex. Admin. Code section 291.29(c)(4) (emphasis added). Regarding recordkeeping, inventory, and storage, Texas pharmacies are required to keep and maintain accurate and timely records of the inventory and distribution of controlled substances—including “a perpetual inventory of any controlled substance listed in Schedule II”—and such documentation must be readily available upon request or inspection. *Id.* section 291.75(a)(1), (c)(4)–(5).

In the current matter, the Agency agrees with the ALJ’s analysis that Respondent’s dispensing fell below the Texas standard of care—and thus was outside the usual course of professional practice—because, as detailed above, Respondent repeatedly filled

prescriptions for controlled substances for multiple patients without adhering to Texas’ operational standards for pharmacists filling prescriptions and without addressing or resolving numerous and blatant red flags of abuse and/or diversion;³¹ in addition, Respondent repeatedly failed in its obligations regarding recordkeeping, inventory, and storage.³² *Id.* at 42–44, 49–50, 53–55, 59–62. As Respondent’s conduct displays clear violations of the Federal and State regulations described above, the Agency agrees with the ALJ and hereby finds that Respondent repeatedly violated Federal and State law relating to controlled substances. *Id.* Accordingly, the Agency agrees with the ALJ and finds that Factors B and D weigh in favor of revocation of Respondent’s registration and thus finds Respondent’s continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). *Id.* at 61–62.

III. Sanction

Where, as here, the Government has established sufficient grounds to revoke Respondent’s registration, the burden shifts to the registrant to show why it can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18882, 18910 (2018). When a registrant has committed acts inconsistent with the public interest, it must both accept responsibility and demonstrate that it has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195*, 77FR 62316, 62339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the

²⁷ Further, Federal law “prohibit[s] a pharmacist from filling a prescription for a controlled substance when he either knows or has reason to know that the prescription was not written for a legitimate medical purpose.” *Id.*

²⁸ Registrants are required to take an “initial inventory,” meaning an “inventory of all stocks of controlled substances on hand on the date [they] first engage[] in the manufacture, distribution, or dispensing of controlled substances . . .”; “[a]fter the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years” and this “biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.” *Id.* § 1304.11(b)–(c).

²⁹ Texas law states that “[a] pharmacist may not . . . dispense a controlled substance if the pharmacist knows or should have known that the prescription was issued without a valid patient-practitioner relationship.” *Id.* section 481.074(a)(2). Further, it is unlawful in Texas for any “registrant or dispenser” to knowingly deliver a controlled substance in violation of sections 481.070–481.075 of the Texas Health and Safety Code. *Id.* section 481.128. Texas regulations require that a Texas pharmacist “shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order” and “shall make every reasonable effort to ensure that any prescription drug order . . . has been issued for a legitimate medical purpose by a practitioner in the course of medical practice.” 22 Tex. Admin. Code sections 291.29(a)–(b), 291.34(b)(1).

³⁰ Such documentation must be “on the prescription or in the pharmacy’s data processing system associated with the prescription . . . and shall include . . . (i) [the] date the prescriber was consulted; (ii) [the] name of the person communicating the prescriber’s instructions; (iii) any applicable information pertaining to the consultation; and (iv) [the] initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.” *Id.* section 291.33(c)(2)(C).

³¹ Although Ms. Salinas opined that different apartment or unit numbers at the same address would be considered a shared address red flag under the Texas standard of care, see *supra*, the ALJ found that “[w]hile different apartments in the same building or complex may share the same street number, the unit or apartment number that completes the address makes them unique addresses.” RD, at 54. However, the Agency has previously agreed with Ms. Salinas and found that different apartment or unit numbers at the same address constituted the shared address red flag under the Texas standard of care when the patients in question were receiving prescriptions for the same controlled substances from the same prescribers. *Blue Mint Pharmacy*, 88 FR 75326, 75327–75328 (2023).

³² The Agency also agrees with the ALJ’s conclusions that none of Respondent’s arguments to the contrary, as detailed above, refute this analysis. RD, at 42–44, 48–50, 57–60.

Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.*, 86 FR 33738, 33746 (2021).

Here, and as noted by the ALJ, Respondent, through its owner, admitted fault for its failure to maintain adequate inventories and failure to properly store controlled substances at its registered location.³³ RD, at 63–64; Tr. 338–339, 348–349, 354. However, Respondent completely “failed to acknowledge [its] errors in handling prescriptions with red flags” and did not “accept responsibility for failing to identify, resolve, and document red flags.” RD, at 64–65. As such, the ALJ concluded, and the Agency agrees, that Respondent has not demonstrated unequivocal acceptance of responsibility for its actions. RD, at 64 (citing *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.*, 81 FR 79188, 79201–202 (2016)).

When a registrant fails to make the threshold showing of acceptance of responsibility, the Agency need not address the registrant's remedial measures. *Ajay S. Ahuja, M.D.*, 84 FR 5479, 5498 n.33 (2019) (citing *Jones Total Health Care Pharmacy*, 81 FR at 79202–303); *Daniel A. Glick, D.D.S.*, 80 FR 74800, 74801, 74810 (2015). Even so, in the current matter, Respondent did not provide any evidence of remedial measures related to its improper dispensing that demonstrate that Respondent would be able to spot, resolve, and document resolution of red flags in the future. The ALJ noted, and the Agency has considered, that Respondent's owner testified, without documentary corroboration, that since the June 2022 inspection, Respondent has updated its “perpetual inventory” on a daily basis and keeps its controlled substances locked in the registered location's safe. RD, at 65 n.120; Tr. 345, 349. However, “remediation alone is not adequate to avoid a sanction and [] limited-to-no-weight is given to remedial measures when the effort is not made until after enforcement begins.” *Morris & Dickson Co., LLC*, 88 FR 34523, 34540 (2023).³⁴ Moreover,

because the Respondent has not presented evidence of any remedial measures for its egregious dispensing failures, the Agency cannot entrust Respondent with a registration.

In addition to acceptance of responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.*, 80 FR at 74810. In this case, the Agency agrees with the ALJ that given that Respondent's pharmacist-in-charge filled every single prescription at issue and that Respondent's owner testified that she was present for and involved in all filling of prescriptions, yet both individuals failed to acknowledge that any red flags existed or required resolution, “the interests of specific deterrence, even standing alone, motivate powerfully in favor of revocation.” RD, at 66–67; Tr. 321, 328–331. Further, the Agency agrees with the ALJ that the interests of general deterrence also support revocation, as a lack of sanction in the current matter would send a message to the registrant community that the failure to properly address and document resolution of red flags, the failure to keep adequate inventories, and/or the failure to securely store controlled substances can be excused. RD, at 67.

Moreover, the Agency agrees with the ALJ that Respondent's actions were egregious. *Id.* at 66. As stated by the ALJ, “Respondent dispensed many controlled substances over a one-and-a-half-year period without any regard for its obligations to identify, resolve, or document any blatant red flags of potential diversion” and with awareness of both its obligations and the existence of numerous red flags in the prescriptions that it was filling and dispensing. *Id.*; Tr. 310, 364–365, 367, 370. Further, regarding recordkeeping, inventory, and storage, Respondent not only failed to maintain proper inventories, thereby “precluding the ability of DEA to conduct an accountability audit,” but also failed to properly store controlled substances at its registered location, with Respondent's owner instead transporting and storing controlled substances at a personal residence in complete disregard of security requirements. RD, at 66.

48887, 48897 (2011) (“The Agency has recognized that a cessation of illegal behavior only when ‘DEA comes knocking at one’s door,’ can be afforded a diminished weight borne of its own opportunistic timing.”); *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36503 (2007) (giving no weight to respondent's “stroke-of-midnight decision” to cease supplying suspect pharmacies with controlled substances and to employ a compliance officer).

In sum, Respondent has not offered any credible evidence on the record that rebuts the Government's case for revocation of its registration and Respondent has not demonstrated that it can be entrusted with the responsibility of registration. *Id.* at 67. Accordingly, the Agency will order that Respondent's registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FM2396427 issued to Midtown Specialty RX. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Midtown Specialty RX to renew or modify this registration, as well as any other pending application of Midtown Specialty RX for additional registration in Texas. This Order is effective November 12, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 4, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–23482 Filed 10–9–24; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Halowells Pharmacy; Decision and Order

On November 8, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Halowells Pharmacy (Registrant) of Pearland, Texas. Request for Final Agency Action (RFAA), Exhibit (RFAAX) A, at 1. The OSC/ISO informed Registrant of the immediate suspension of its DEA Certificate of Registration, Control No.

³³ While Respondent clearly violated both Federal and State law by failing to have inventories on hand during the June 2022 inspection, Respondent has accepted responsibility for and taken steps to remediate this particular violation. Respondent has also accepted responsibility, though perhaps not unequivocally, and attempted to remediate the improper storage of controlled substances at her home. However, acceptance of responsibility and remedial steps regarding these two violations does not lead the Agency to reduce the sanction here, because the evidence shows that Respondent has not unequivocally accepted responsibility nor taken any steps to remediate the egregious dispensing violations. *See infra*.

³⁴ Citing *Mireille Lalanne, M.D.*, 78 47750, 47777 (2013) (quoting *Liddy's Pharmacy, L.L.C.*, 76 FR

FH9037830, pursuant to 21 U.S.C. 824(d), alleging that Registrant's continued registration constitutes "'an imminent danger to the public health or safety.'" *Id.* (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Registrant's registration, alleging that Registrant's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 823(g)(1), 824(a)(4)).

The OSC/ISO notified Registrant of its right to file with DEA a written request for hearing, and that if it failed to file such a request, it would be deemed to have waived its right to a hearing and be in default. *Id.* at 9 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.¹ "A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC/ISO]." 21 CFR 1301.43(e).

Further, "[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67." *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), 1301.46. RFAA, at 3; *see also* 21 CFR 1316.67.

I. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC/ISO are admitted.² Registrant is deemed to have admitted that it repeatedly dispensed prescriptions in violation of the minimum practice standards that govern pharmacy practice in Texas. RFAAX A, at 4. Specifically, from at least January 2022 through July 2023, Registrant repeatedly filled controlled substance prescriptions that contained multiple red flags of abuse and/or diversion without addressing or resolving the red

flags, in violation of both Federal and State law. *Id.* at 4–5.

A. Pattern Prescribing

Texas regulations identify the following prescribing patterns as red flag factors: Dispensing to numerous persons substantially identical prescriptions by the same prescriber for the same controlled substances; a prescriber's prescriptions are routinely for controlled substances commonly known to be abused drugs, including opioids; and a prescriber's prescriptions for controlled substances are commonly for the highest strength of the drug and/or for large quantities (e.g., monthly supply). 22 Tex. Admin. Code section 291.29(f)(1), (3), (5); RFAAX A, at 3–4.

Registrant is deemed to have admitted that it failed to identify and resolve the red flag that occurs when a practitioner prescribes the same controlled substance in identical or substantially similar quantities to multiple patients. RFAAX A, at 5. Specifically, between January 2022 and June 2023, Registrant filled over 90 prescriptions for oxycodone issued by Dr. V.M. to C.W., D.S.T., D.W., E.W., J.L., J.R., and L.T. *Id.* Each prescription was for the highest strength of oxycodone, 30 mg, which is known to be frequently abused, and each prescription ranged from 98 to 105 dosage units. *Id.*

Further, between January 2022 and June 2023, Registrant filled over 30 prescriptions for hydrocodone-acetaminophen issued by Dr. V.M. to D.S.E., D.S.M., and J.J. *Id.* Each prescription was for the highest strength of hydrocodone-acetaminophen, 10/325 mg, which is known to be frequently abused, and the prescriptions ranged from 90 to 105 dosage units. *Id.*

Accordingly, the Agency finds that Registrant filled over 120 controlled substance prescriptions without first resolving the pattern prescribing red flags.

B. Prescriptions Lacking Specific Diagnosis

Texas regulations identify the following prescribing pattern as a red flag factor: "[P]rescriptions for controlled substances by a prescriber presented to the pharmacy contain nonspecific or no diagnoses, or lack the intended use of the drug." 22 Tex. Admin. Code section 291.29(f)(4); RFAAX A, at 3.

Registrant is deemed to have admitted that it failed to identify and resolve the red flag of prescriptions lacking a specific diagnosis. RFAAX A, at 5. Specifically, between January 2022 and June 2023, Registrant filled prescriptions lacking specific diagnoses

for all ten individuals³ for oxycodone 30 mg and hydrocodone-acetaminophen 10/325 mg. *Id.* Accordingly, the Agency finds that Registrant filled controlled substance prescriptions without first resolving the red flag of prescriptions lacking a specific diagnosis.

C. Shared Addresses

Texas regulations identify the following prescribing pattern as a red flag factor: "[M]ultiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner." 22 Tex. Admin. Code section 291.29(f)(11); RFAAX A, at 4.

Registrant is deemed to have admitted that it failed to identify and resolve the red flag of multiple persons with the same address presenting the same, or substantially similar, prescriptions from the same practitioner. RFAAX A, at 6. Specifically, between January 2022 and June 2023, Registrant filled prescriptions for oxycodone 30 mg for C.W. and D.W., who both share the same address and received their prescriptions from the same practitioner, Dr. V.M. *Id.* Between January 2022 and April 2023, Registrant filled prescriptions for hydrocodone-acetaminophen 10/325 mg for D.S.M. and J.J., who both share the same address and received their prescriptions from the same practitioner, Dr. V.M. *Id.* Between February 2022 and June 2023, Registrant filled prescriptions for oxycodone 30 mg for J.R. and L.T., who both share the same address and received their prescriptions from the same practitioner, Dr. V.M. *Id.* Finally, between January 2022 and May 2023, Registrant filled prescriptions for hydrocodone-acetaminophen 10/325 mg for D.S.E. and J.L.,⁴ who both share the same address and received their prescriptions from the same practitioner, Dr. V.M. *Id.*

Accordingly, the Agency finds that Registrant filled controlled substance prescriptions without first resolving the red flag of shared addresses.

³ C.W., D.S.E., D.S.M., D.S.T., D.W., E.W., J.J., J.L., J.R., and L.T., the relevant individuals to whom prescriptions were improperly filled in this case, are referred to collectively as the ten individuals.

⁴ The OSC also alleges, and it is therefore admitted, that Registrant filled oxycodone 30 mg for D.S.T. who shared an address with D.S.E. and J.L. and saw the same practitioner. *Id.* This allegation is not sustained because there is not substantial evidence or an admission that clearly establishes that hydrocodone-acetaminophen 10/325 is a "substantially similar controlled substance prescription" to oxycodone 30 mg such that the prescription presents an additional instance of the shared address red flag. *Id.*

¹ Based on the Government's submissions in its RFAA dated January 4, 2024, the Agency finds that service of the OSC/ISO on Registrant was adequate and rendered on November 16, 2023. Specifically, the Government included as an attachment to its RFAA a Form DEA-12 signed by a representative of Registrant, indicating that Registrant was personally served with the OSC/ISO on November 16, 2023. RFAA, at 1–2; RFAAX B.

² The Agency need not adjudicate the criminal violations alleged in the instant OSC/ISO. *Ruan v. United States*, 142 S. Ct. 2,370 (2022) (decided in the context of criminal proceedings).

D. Prescriber Area of Practice

Texas regulations identify the following prescribing pattern as a red flag factor: “[T]he controlled substance(s) or the quantity of the controlled substance(s) prescribed are inconsistent with the practitioner’s area of medical practice.” 22 Tex. Admin. Code section 291.29(f)(9); RFAAX A, at 6. Registrant is deemed to have admitted that between January 2022 and June 2023, Registrant repeatedly filled prescriptions for oxycodone and hydrocodone-acetaminophen issued by Dr. V.M., despite Dr. V.M. prescribing outside of her family and administrative medicine area of practice. RFAAX A, at 6.⁵ Accordingly, the Agency finds that Registrant filled controlled substance prescriptions without first resolving the red flag arising from the prescriber’s area of practice.

E. Long Distances

Registrant is deemed to have admitted that individuals traveling long distances to obtain or fill controlled substance prescriptions is a well-known red flag of abuse or diversion. Registrant further admits that it repeatedly filled prescriptions without identifying and resolving the red flag of patients traveling long distances to obtain or fill controlled substance prescriptions. *Id.* at 7. Specifically, Registrant is deemed to have admitted that it filled prescriptions for seven individuals, C.W., D.W., D.S.M., J.J., E.W., J.R., and L.T., whose residences were in “completely opposite areas of the Houston Metropolitan area” from their physician’s office (Dr. V.M.) and from their pharmacy (Registrant). *Id.* Registrant further admits that there were several pharmacies closer to both Dr. V.M.’s office and the seven individuals’ residences. *Id.*

Accordingly, the Agency finds that Registrant filled controlled substance prescriptions without first resolving the

red flag arising from long distances traveled.

F. Cash Payments

Texas regulations identify the following prescribing pattern as a red flag factor: “[P]ersons consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance.” 22 Tex. Admin. Code section 291.29(f)(12); RFAAX A, at 7–8.

Registrant is deemed to have admitted that it failed to identify and resolve the red flag of cash payments, which is a common red flag because it allows a patient to avoid the scrutiny associated with the use of insurance. *Id.* at 7–8. Specifically, between January 2022 and July 2023, Registrant routinely accepted cash payments for controlled substance prescriptions, including for each of the prescriptions filled for each of the ten individuals as described above. *Id.* at 8. Registrant is also deemed to have admitted that for L.T., Registrant routinely accepted cash payment for L.T.’s prescriptions between February 2022 and July 2023, despite the Texas Prescription Drug Monitoring Program Report indicating that L.T. used insurance at other pharmacies on three occasions.⁶ *Id.*

Accordingly, the Agency finds that Registrant filled controlled substance prescriptions without first resolving the red flag arising from cash payments.

G. Expert Review

DEA retained an independent pharmacy expert who concluded that the above prescription data presented multiple red flags that were highly indicative of abuse and diversion. *Id.* Registrant is deemed to have admitted that these red flags were not resolved by a pharmacist acting in the usual course of professional practice prior to dispensing, and, therefore, that each

prescription was filled outside the Texas standard of care. *Id.*

II. Discussion

A. The Five Public Interest Factors

Under the Controlled Substances Act (CSA), “[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under [21 CFR 823] inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The [registrant]’s experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant]’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1).

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enf’t Admin.*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993).

While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1),⁷ the Government’s evidence in support of its *prima facie* case for revocation of Registrant’s registration is confined to Factors B and D. *See*

⁵ Texas regulations further identify as a red flag pattern, “[T]he practitioner’s clinic is not registered as, and not exempted from registration as, a pain management clinic by the Texas Medical Board, despite prescriptions by the practitioner presented to the pharmacy indicating that the practitioner is mostly prescribing opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone, or any combination of these drugs.” 22 Tex. Admin. Code section 291.29(f)(8). The OSC alleges, and it is therefore deemed admitted, that “Dr. [V.M.] is not Board Certified in the area of pain management.” RFAAX A, at 6. However, there is not substantial evidence or an admission that the prescriptions issued by Dr. V.M. that were presented to the Registrant were *mostly* for opioids and the other listed controlled substances. Accordingly, the Agency cannot sustain this allegation or find that it presents an additional instance of the prescriber area of practice red flag.

⁶ The OSC additionally alleged, and it is therefore deemed admitted, that “between January 2022 and July 2023, [Registrant] routinely dispensed a quantity less than the amount prescribed by the physician and provided no documentation regarding approval from the physician.” *Id.* The OSC implies that this conduct violates 22 Texas Administrative Code section 291.33(c)(2)(A)(iv), which states: “[P]rior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained” *Id.* It is not clear from substantial record evidence or an admission that the Registrant filling a quantity less than what was prescribed means that Registrant must have had unresolved questions regarding the prescription drug order. Accordingly, this allegation regarding the red flag of dispensing less than prescribed is not sustained. The Agency finds that the founded allegations discussed above are more than sufficient to support the Government’s requested sanction of revocation under these circumstances.

⁷ As to Factor A, the record contains no evidence of a recommendation from any State licensing board or professional disciplinary authority. 21 U.S.C. 823(g)(1)(A). Nonetheless, an absence of such evidence “does not weigh for or against a determination as to whether continuation of the [registrant’s] DEA certification is consistent with the public interest.” *Roni Dreszer, M.D.*, 76 FR 19434, 19444 (2011). As to Factor C, there is no evidence in the record that Registrant has been convicted of an offense under either Federal or State law “relating to the manufacture, distribution, or dispensing of controlled substances.” 21 U.S.C. 823(g)(1)(C). Agency cases have found that “the absence of such a conviction is of considerably less consequence in the public interest inquiry” and is therefore not dispositive. *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010). Finally, as to Factor E, the Government’s evidence fits squarely within the parameters of Factors B and D and does not raise “other conduct which may threaten the public health and safety.” 21 U.S.C. 823(g)(1)(E). Accordingly, Factor E does not weigh for or against Registrant.

RFAAX A, at 4–5. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Here, the Agency finds that the Government's evidence satisfies its *prima facie* burden of showing that Registrant's continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4).

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See Suaaleh Ashraf, M.D.*, 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022). In the current matter, the Government has alleged that Registrant violated both Federal and State law regulating controlled substances. RFAAX A, at 2–4. Specifically, a pharmacist may only fill a prescription that was "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *Id.* § 1306.04(a). Although "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* Section 1306.04(a) prohibits "a pharmacist from filling a prescription for a controlled substance when he either knows or has reason to know that the prescription was not written for a legitimate medical purpose." *Wheatland Pharmacy*, 78 FR 69441, 69445 (2013) (internal quotations and alterations omitted); RFAAX 2, at 2. DEA regulations require "pharmacists to identify and resolve suspicions that a prescription is illegitimate." *Trinity Pharmacy II*, 83 FR 7304, 7331 (2018); RFAAX 2, at 2. Further, under Federal regulations, a prescription for a controlled substance "may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 CFR 1306.06.

As for State law, under Texas regulations, "[a] pharmacist may not dispense . . . a controlled substance . . . except under a valid prescription and in the course of professional practice." Tex. Health & Safety Code section 481.074(a). Regarding the specific standards for a pharmacist filing a new or refill prescription, "[f]or the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant: . . . (III)

reasonable dose and route of administration; . . . (VI) drug-drug interactions; . . . [and] (X) proper utilization, including overutilization or underutilization." 22 Tex. Admin. Code section 291.33(c)(2)(A)(i). "Upon identifying any clinically significant conditions [or] situations . . . the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner." *Id.* section 291.33(c)(2)(A)(ii). "Prior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained." *Id.* section 291.33(c)(2)(A)(iv); *see also id.* sections 291.29(a)–(b), 291.33(c)(2)(C) (describing the requirements for documentation).

Regarding "red flag factors" that are "relevant to preventing the non-therapeutic dispensing of controlled substances," Texas regulations identify the following relevant circumstances as red flags:

(1) the pharmacy dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances, potentially paired with other drugs, for numerous persons, indicating a lack of individual drug therapy in prescriptions issued by the practitioner; . . .

(3) prescriptions by a prescriber presented to the pharmacy are routinely for controlled substances commonly known to be abused drugs, including opioids, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups containing codeine, or any combination of these drugs;

(4) prescriptions for controlled substances by a prescriber presented to the pharmacy contain nonspecific or no diagnoses, or lack the intended use of the drug;

(5) prescriptions for controlled substances are commonly for the highest strength of the drug and/or for large quantities (e.g., monthly supply), indicating a lack of individual drug therapy in prescriptions issued by the practitioner; . . .

(8) the practitioner's clinic is not registered as, and not exempted from registration as, a pain management clinic by the Texas Medical Board, despite prescriptions by the practitioner presented to the pharmacy indicating that the practitioner is mostly prescribing opioids . . . ;

(9) the controlled substance(s) or the quantity of the controlled substance(s) prescribed are inconsistent with the practitioner's area of medical practice; . . .

(11) multiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner; [and]

(12) persons consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance."

Id. section 291.29(f). Further, under Texas regulations, "[a] pharmacist shall not dispense a prescription drug if the pharmacist knows or should know the prescription drug order is fraudulent or forged." *Id.*

Here, Registrant has admitted that it repeatedly filled prescriptions for controlled substances that contained multiple red flags of abuse and/or diversion without addressing or resolving those red flags. RFAAX A, at 5–8. DEA's pharmacy expert concluded that these red flags were highly indicative of abuse and diversion. *Id.* at 8. Registrant has further admitted that none of the above-referenced controlled substance prescriptions were filled for a legitimate medical purpose in the usual course of professional practice. *Id.* As such, the Agency finds that Registrant violated 21 CFR 1306.04, 1306.06, Texas Health & Safety Code section 481.074, and 22 Texas Administrative Code sections 291.29, 291.33.

Accordingly, the Agency finds that Factors B and D weigh in favor of revocation of Registrant's registration and thus finds Registrant's continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). The Agency further finds that Registrant failed to provide any evidence to rebut the Government's *prima facie* case.

III. Sanction

Where, as here, the Government has established grounds for revocation, the burden shifts to the registrant to show why it can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18882, 18910 (2018). To establish that it can be entrusted with registration, a registrant must both accept responsibility and demonstrate that it has undertaken corrective measures. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 FR 62316, 62339 (2012) (internal quotations omitted); *see also Michele L. Martinho, M.D.*, 86 FR 24012, 24019 (2021); *George D. Gowder, III, M.D.*, 89 FR 76152, 76154 (2024). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.*, 86 FR 33738, 33746 (2021).

Here, Registrant failed to answer the allegations contained in the OSC/ISO

and did not otherwise avail itself of the opportunity to refute the Government's case. As such, Registrant has made no representations as to its future compliance with the CSA nor made any demonstration that it can be entrusted with registration. Moreover, the evidence presented by the Government shows that Registrant violated the CSA, further indicating that Registrant cannot be entrusted.

Accordingly, the Agency will order the revocation of Registrant's registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FH9037830 issued to Halowells Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Halowells Pharmacy to renew or modify this registration, as well as any other pending application of Halowells Pharmacy for additional registration in Texas. This Order is effective November 12, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 4, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024-23495 Filed 10-9-24; 8:45 am]

BILLING CODE 4410-09-P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; Louis Stokes Alliances for Minority Participation (LSAMP) Program Evaluation; Withdrawal

AGENCY: National Science Foundation (NSF).

ACTION: Notice; withdrawal.

SUMMARY: The National Science Foundation published a notice in the **Federal Register** on September 23, 2024, that was inadvertently sent forward to publish and is a duplicate (with errors) of a notice published on October 2, 2024.

FOR FURTHER INFORMATION CONTACT:

Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314; telephone (703) 292-7556; or send email to splimpto@nsf.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

SUPPLEMENTARY INFORMATION:

Background

On September 23, 2024, the National Science Foundation published in the **Federal Register** a notice for comments (FR Doc 2024-21845) that was inadvertently published (with errors) and is a duplicate of a notice published October 2, 2024 (FR Doc 2024-22588).

Retraction

From the **Federal Register** of September 23, 2024, the notice in the second column of page 77898 to the second column of 77899, is withdrawn (FR Doc 2024-21845). As such, FR Doc 2024-21845 should be disregarded.

Dated: October 4, 2024.

Suzanne H. Plimpton,
Reports Clearance Officer, National Science Foundation.

[FR Doc. 2024-23420 Filed 10-9-24; 8:45 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

720th Meeting of the Advisory Committee on Reactor Safeguards (ACRS)

In accordance with the purposes of sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232(b)), the Advisory Committee on Reactor Safeguards (ACRS) will hold meetings on November 6-8, 2024. The Committee will be conducting meetings that will include some Members being physically present at the NRC while other Members participate remotely. Interested members of the public are encouraged to participate remotely in any open sessions via MS Teams or via phone at 301-576-2978, passcode 887 935 620#. A more detailed agenda including the

MSTeams link may be found at the ACRS public website at <https://www.nrc.gov/reading-rm/doc-collections/acrs/agenda/index.html>. If you would like the MSTeams link forwarded to you, please contact the Designated Federal Officer (DFO) as follows: Quynh.Nguyen@nrc.gov, or Lawrence.Burkhart@nrc.gov.

Wednesday, November 6, 2024

8:30 a.m.–8:35 a.m.: *Opening Remarks by the ACRS Chair (Open)*—The ACRS Chair will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:30 a.m.: *Draft White Paper, “Nth-of-a-Kind Micro-Reactor Licensing and Deployment Considerations” (Open)*—The Committee will have presentations and discussion with the NRC staff regarding the subject topic.

10:30 a.m.–1:00 p.m.: *Committee Deliberation on Draft White Paper, “Nth-of-a-Kind Micro-Reactor Licensing and Deployment Considerations” (Open)*—The Committee will deliberate with the NRC staff regarding the subject topic.

1:00 p.m.–6:00 p.m.: *Triennial Review and Evaluation of NRC Safety Research Program/Preparation of Reports (Open)*—The Committee will have presentations and discussion with the NRC staff regarding the subject topic.

Thursday, November 7, 2024

8:30 a.m.–10:15 a.m.: *TerraPower Sodium Topical Report on Plume Exposure Pathway Emergency Planning Zone (Open/Closed)*—The Committee will have presentations and discussion with the NRC staff regarding the subject topic.

[Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

10:15 a.m.–11:15 a.m.: *Committee Deliberation on the TerraPower Sodium Topical Report on Plume Exposure Pathway Emergency Planning Zone (Open/Closed)*—The Committee will deliberate with the NRC staff regarding the subject topic.

[Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

1:15 p.m.–6:00 p.m.: *Planning and Procedures Session/Future ACRS Activities/Reconciliation of ACRS Comments and Recommendations/Preparation of Reports (Open/Closed)*—The Committee will hear discussion of the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the

Full Committee during future ACRS meetings, and/or proceed to preparation of reports.

[Note: Pursuant to 5 U.S.C. 552b(c)(2), a portion of this meeting may be closed to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS.]

[Note: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

Friday, November 8, 2024

8:30 a.m.–6:00 p.m.: Committee Deliberation and Preparation of Reports (Open)—The Committee will proceed to preparation of reports and Committee deliberation.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on June 13, 2019 (84 FR 27662). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff and the DFO (Telephone: 301–415–5844, Email: Quynh.Nguyen@nrc.gov), 5 days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chair as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the cognizant ACRS staff if such rescheduling would result in major inconvenience.

An electronic copy of each presentation should be emailed to the cognizant ACRS staff at least one day before the meeting.

In accordance with subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chair. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room (PDR) at pdr.resource@nrc.gov, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System component of NRC's Agencywide Documents Access and Management System, which is accessible from the NRC website at

<https://www.nrc.gov/reading-rm/adams.html> or <https://www.nrc.gov/reading-rm/doc-collections/#ACRS/>.

Dated: October 4, 2024.

Russell E. Chazell,

Federal Advisory Committee Management Officer, Office of the Secretary.

[FR Doc. 2024–23424 Filed 10–9–24; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

International Product Change—Priority Mail Express International, Priority Mail International & First-Class Package International Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a Priority Mail Express International, Priority Mail International & First-Class Package International Service contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: Date of notice: October 10, 2024.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on October 2, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 47 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–3 and K2025–3.

Colleen Hibbert-Kapler,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2024–23411 Filed 10–9–24; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101249; File No. SR–NYSEAMER–2024–59]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend the Connectivity Fee Schedule

October 4, 2024.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (“Act”)² and Rule 19b–4 thereunder,³ notice is hereby given that, on September 20, 2024, NYSE American LLC (“NYSE American” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule (“Fee Schedule”) to delete the currently-filed “Optic Low Latency Circuit—1 Gb” service as obsolete. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule ("Fee Schedule") to delete the currently-filed "Optic Low Latency Circuit—1 Gb" service as obsolete.

In 2023, the Exchange filed to amend the Fee Schedule to add several "FIDS Circuits" available at the Mahwah, New Jersey data center ("MDC"),⁴ including Optic Low Latency Circuits in 1 Gb, 10 Gb, and 40 Gb sizes.⁵

Since that time, no Users⁶ have opted to utilize the 1 Gb Optic Low Latency Circuit. Some market participants have informed the Exchange that the 1 Gb size of the Optic Low Latency Circuit is too small for their needs. Because there is no customer demand for the 1 Gb Optic Low Latency Circuit, the Exchange proposes to discontinue the service as obsolete.

General

The proposed changes would not apply differently to distinct types or sizes of market participants; rather, they would apply to all Users equally. As is currently the case, the Fee Schedule would be applied uniformly to all Users. The proposed changes are not intended to address any other issues and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁷ in general, and furthers the objectives of Section 6(b)(5)

of the Act,⁸ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that discontinuing offering the 1 Gb Optic Low Latency Circuit would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Demand for the 1 Gb Optic Low Latency Circuit is non-existent and there are currently no customers that subscribe to the service. The Exchange does not expect demand to rebound given customers' assessment that the 1 Gb-size of the circuit is too small for their needs. Removing references to the fees for this obsolete service from the Fee Schedule would make the Fee Schedule easier to read, understand, and administer.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would delete an obsolete service from the Fee Schedule, which would enhance transparency and alleviate potential customer confusion.

The Exchange believes that removing this obsolete service from the Fee Schedule would not permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed changes would apply equally to all Users: the obsolete 1 Gb Optic Low Latency Circuit would be removed for all customers.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.⁹ The proposed rule change is not designed to address any competitive issues but rather is designed to enhance

the clarity and transparency of the Fee Schedule and alleviate possible customer confusion that may arise from the inclusion of obsolete services.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹²

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

¹⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6)(iii). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹³ 15 U.S.C. 78s(b)(2)(B).

⁴ Through its Fixed Income and Data Services ("FIDS") (previously ICE Data Services) business, Intercontinental Exchange, Inc. ("ICE") operates the MDC. The Exchange and New York Stock Exchange LLC, NYSE Arca, Inc., NYSE Chicago, Inc. and NYSE National, Inc. (together, the "Affiliate SROs") are indirect subsidiaries of ICE.

⁵ See Securities Exchange Act Release No. 99179 (December 14, 2023), 88 FR 88155 (December 20, 2023) (SR-NYSEAMER-2023-65).

⁶ For purposes of the Exchange's colocation services, a "User" means any market participant that requests to receive colocation services directly from the Exchange. See Securities Exchange Act Release No. 76009 (September 29, 2015), 80 FR 60213 (October 5, 2015) (SR-NYSEMKT-2015-67). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs. Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. See SR-NYSE-2024-61, SR-NYSEARCA-2024-81, SR-NYSECHX-2024-30, and SR-NYSENAT-2024-27.

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

⁹ 15 U.S.C. 78f(b)(8).

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEAMER-2024-59 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSEAMER-2024-59. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEAMER-2024-59 and should be submitted on or before October 31, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024-23413 Filed 10-9-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101250; File No. SR-NYSEARCA-2024-81]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

October 4, 2024.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 ("Act") ² and Rule 19b-4 thereunder,³ notice is hereby given that, on September 20, 2024, NYSE Arca, Inc. ("NYSE Arca" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule ("Fee Schedule") to delete the currently-filed "Optic Low Latency Circuit—1 Gb" service as obsolete. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule ("Fee Schedule") to delete the currently-filed "Optic Low Latency Circuit—1 Gb" service as obsolete.

In 2023, the Exchange filed to amend the Fee Schedule to add several "FIDS Circuits" available at the Mahwah, New Jersey data center ("MDC"),⁴ including Optic Low Latency Circuits in 1 Gb, 10 Gb, and 40 Gb sizes.⁵

Since that time, no Users⁶ have opted to utilize the 1 Gb Optic Low Latency Circuit. Some market participants have informed the Exchange that the 1 Gb size of the Optic Low Latency Circuit is too small for their needs. Because there is no customer demand for the 1 Gb Optic Low Latency Circuit, the Exchange proposes to discontinue the service as obsolete.

General

The proposed changes would not apply differently to distinct types or sizes of market participants; rather, they would apply to all Users equally. As is currently the case, the Fee Schedule would be applied uniformly to all Users. The proposed changes are not intended to address any other issues and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁷ in general, and furthers the objectives of Section 6(b)(5)

⁴ Through its Fixed Income and Data Services ("FIDS") (previously ICE Data Services) business, Intercontinental Exchange, Inc. ("ICE") operates the MDC. The Exchange and New York Stock Exchange LLC, NYSE American LLC, NYSE Chicago, Inc. and NYSE National, Inc. (together, the "Affiliate SROs") are indirect subsidiaries of ICE.

⁵ See Securities Exchange Act Release No. 99166 (December 14, 2023), 88 FR 88178 (December 20, 2023) (SR-NYSEARCA-2023-83).

⁶ For purposes of the Exchange's colocation services, a "User" means any market participant that requests to receive colocation services directly from the Exchange. See Securities Exchange Act Release No. 76010 (September 29, 2015), 80 FR 60197 (October 5, 2015) (SR-NYSEARCA-2015-82). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs. Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. See SR-NYSE-2024-61, SR-NYSEAMER-2024-59, SR-NYSECHX-2024-30, and SR-NYSEENAT-2024-27.

⁷ 15 U.S.C. 78f(b).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

¹⁴ 17 CFR 200.30-3(a)(12).

of the Act,⁸ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that discontinuing offering the 1 Gb Optic Low Latency Circuit would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Demand for the 1 Gb Optic Low Latency Circuit is non-existent and there are currently no customers that subscribe to the service. The Exchange does not expect demand to rebound given customers' assessment that the 1 Gb-size of the circuit is too small for their needs. Removing references to the fees for this obsolete service from the Fee Schedule would make the Fee Schedule easier to read, understand, and administer.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would delete an obsolete service from the Fee Schedule, which would enhance transparency and alleviate potential customer confusion.

The Exchange believes that removing this obsolete service from the Fee Schedule would not permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed changes would apply equally to all Users: the obsolete 1 Gb Optic Low Latency Circuit would be removed for all customers.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.⁹ The proposed rule change is not designed to address any competitive issues but rather is designed to enhance

the clarity and transparency of the Fee Schedule and alleviate possible customer confusion that may arise from the inclusion of obsolete services.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹²

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

¹⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6)(iii). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹³ 15 U.S.C. 78s(b)(2)(B).

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEARCA-2024-81 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSE-SR-NYSEARCA-2024-81. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-SR-NYSEARCA-2024-81 and should be submitted on or before October 31, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024-23414 Filed 10-9-24; 8:45 am]

BILLING CODE 8011-01-P

¹⁴ 17 CFR 200.30-3(a)(12).

⁸ 15 U.S.C. 78f(b)(5).

⁹ 15 U.S.C. 78f(b)(8).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101253; File No. SR–NYSENAT–2024–27]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

October 4, 2024.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (“Act”) ² and Rule 19b–4 thereunder, ³ notice is hereby given that on September 20, 2024, NYSE National, Inc. (“NYSE National” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule (“Fee Schedule”) to delete the currently-filed “Optic Low Latency Circuit—1 Gb” service as obsolete. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule (“Fee Schedule”) to delete the currently-filed “Optic Low Latency Circuit—1 Gb” service as obsolete.

In 2023, the Exchange filed to amend the Fee Schedule to add several “FIDS Circuits” available at the Mahwah, New Jersey data center (“MDC”), ⁴ including Optic Low Latency Circuits in 1 Gb, 10 Gb, and 40 Gb sizes. ⁵

Since that time, no Users ⁶ have opted to utilize the 1 Gb Optic Low Latency Circuit. Some market participants have informed the Exchange that the 1 Gb size of the Optic Low Latency Circuit is too small for their needs. Because there is no customer demand for the 1 Gb Optic Low Latency Circuit, the Exchange proposes to discontinue the service as obsolete.

General

The proposed changes would not apply differently to distinct types or sizes of market participants; rather, they would apply to all Users equally. As is currently the case, the Fee Schedule would be applied uniformly to all Users. The proposed changes are not intended to address any other issues and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act, ⁷ in general, and furthers the objectives of Section 6(b)(5)

⁴ Through its Fixed Income and Data Services (“FIDS”) (previously ICE Data Services) business, Intercontinental Exchange, Inc. (“ICE”) operates the MDC. The Exchange and New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc. and NYSE Chicago, Inc. (together, the “Affiliate SROs”) are indirect subsidiaries of ICE.

⁵ See Securities Exchange Act Release No. 99168 (December 14, 2023), 88 FR 88152 (December 20, 2023) (SR–NYSENAT–2023–29).

⁶ For purposes of the Exchange’s colocation services, a “User” means any market participant that requests to receive colocation services directly from the Exchange. See Securities Exchange Act Release No. 83351 (May 31, 2018), 83 FR 26314 at n.9 (June 6, 2018) (SR–NYSENAT–2018–07). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs. Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. See SR–NYSE–2024–61, SR–NYSEAMER–2024–59, SR–NYSEARCA–2024–81, and SR–NYSECHX–2024–30.

⁷ 15 U.S.C. 78f(b).

of the Act, ⁸ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that discontinuing offering the 1 Gb Optic Low Latency Circuit would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Demand for the 1 Gb Optic Low Latency Circuit is non-existent and there are currently no customers that subscribe to the service. The Exchange does not expect demand to rebound given customers’ assessment that the 1 Gb-size of the circuit is too small for their needs. Removing references to the fees for this obsolete service from the Fee Schedule would make the Fee Schedule easier to read, understand, and administer.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would delete an obsolete service from the Fee Schedule, which would enhance transparency and alleviate potential customer confusion.

The Exchange believes that removing this obsolete service from the Fee Schedule would not permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed changes would apply equally to all Users: the obsolete 1 Gb Optic Low Latency Circuit would be removed for all customers.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act. ⁹ The proposed rule change is not designed to address any competitive issues but rather is designed to enhance

⁸ 15 U.S.C. 78f(b)(5).

⁹ 15 U.S.C. 78f(b)(8).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

the clarity and transparency of the Fee Schedule and alleviate possible customer confusion that may arise from the inclusion of obsolete services.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹²

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSENAT-2024-27 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSENAT-2024-27. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSENAT-2024-27 and should be submitted on or before October 31, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024-23416 Filed 10-9-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101257; File No. SR-NYSE-2024-35]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend Section 302.00 of the NYSE Listed Company Manual To Exempt Closed-End Funds Registered Under the Investment Company Act of 1940 From the Requirement To Hold Annual Shareholder Meetings

October 4, 2024.

I. Introduction

On June 21, 2024, the New York Stock Exchange LLC ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend Section 302.00 of the NYSE Listed Company Manual ("Manual") to exempt closed-end funds registered under the Investment Company Act of 1940 ("1940 Act")³ from the requirement to hold annual shareholder meetings. The proposed rule change was published for comment in the **Federal Register** on July 9, 2024.⁴ On August 21, 2024, pursuant to Section 19(b)(2) of the Exchange Act,⁵ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁶ The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act⁷ to determine whether to approve or disapprove the proposed rule change.

II. Description of the Proposed Rule Change

Section 102.04 of the Manual sets forth listing requirements for closed-end

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 80a-1 *et seq.*

⁴ See Securities Exchange Act Release No. 100460 (July 3, 2024), 89 FR 56447 ("Notice"). Comments on the proposed rule change are available at: <https://www.sec.gov/comments/sr-nyse-2024-35/srnyse202435.htm>.

⁵ 15 U.S.C. 78s(b)(2).

⁶ See Securities Exchange Act Release No. 100790, 89 FR 68676 (Aug. 27, 2024). The Commission designated October 7, 2024, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

⁷ 15 U.S.C. 78s(b)(2)(B).

¹⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6)(iii). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹³ 15 U.S.C. 78s(b)(2)(B).

¹⁴ 17 CFR 200.30-3(a)(12).

management investment companies registered under the 1940 Act (“CEFs”). Section 302.00 of the Manual (“Section 302.00”) provides that companies listing common stock or voting preferred stock and their equivalents are required to hold an annual shareholders’ meeting for the holders of such securities during each fiscal year. Section 302.00 also sets forth certain exemptions from this annual shareholder meeting requirement.⁸ CEFs listed on the Exchange are currently required to comply with the Section 302.00 annual shareholder meeting requirement and are not subject to an exemption. The Exchange proposes to amend Section 302.00 to exempt CEFs listed under Section 102.04A of the Manual from the requirement to hold an annual shareholder meeting.⁹

III. Proceedings To Determine Whether To Approve or Disapprove SR–NYSE–2024–35 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act¹⁰ to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved.

⁸ Specifically, Section 302.00 exempts from this requirement companies whose only securities listed on the Exchange are non-voting preferred and debt securities, passive business organizations (such as royalty trusts), or securities listed pursuant to NYSE Rule 5.2(j)(2) (Equity Linked Notes), Rule 5.2(j)(3) (Investment Company Units), Rule 5.2(j)(4) (Index-Linked Exchangeable Notes), Rule 5.2(j)(5) (Equity Gold Shares), Rule 5.2(j)(6) (Equity-Index Linked Securities, Commodity-Linked Securities, Currency-Linked Securities, Fixed Income Index-Linked Securities, Futures-Linked Securities and Multifactor Index-Linked Securities), Rule 5.2(j)(8) (Exchange-Traded Fund Shares), Rule 8.100 (Portfolio Depositary Receipts), Rule 8.200 (Trust Issued Receipts), Rule 8.201 (Commodity-Based Trust Shares), Rule 8.202 (Currency Trust Shares), Rule 8.203 (Commodity Index Trust Shares), Rule 8.204 (Commodity Futures Trust Shares), Rule 8.300 (Partnership Units), Rule 8.400 (Paired Trust Shares), Rule 8.600 (Managed Fund Shares), Rule 8.601 (Active Proxy Portfolio Shares), Rule 8.700 (Managed Trust Securities), and Rule 8.900 (Managed Portfolio Shares).

⁹ The Exchange lists closed-end management investment companies that have filed an election to be treated as a business development company under the 1940 Act (“BDCs”) under Section 102.04B of the Manual. The Exchange is not proposing to exempt BDCs listed under Section 102.04B of the Manual from the annual shareholder meeting requirement set forth in Section 302.00.

¹⁰ 15 U.S.C. 78s(b)(2)(B).

Pursuant to Section 19(b)(2)(B) of the Exchange Act,¹¹ the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change’s consistency with the Exchange Act and, in particular, with Section 6(b)(5) of the Exchange Act, which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.¹²

The development and enforcement of meaningful corporate governance exchange listing standards is of substantial importance to financial markets and the investing public, especially given investor expectations regarding the nature of companies that have achieved an exchange listing for their securities and the role of an exchange in overseeing its market and ensuring compliance with its listing standards.¹³ The corporate governance standards embodied in exchange listing standards play an important role in assuring that listed companies observe good governance practices.¹⁴

In particular, the Commission has consistently recognized the importance of the annual shareholder meeting requirement to the protection of investors and the public interest.¹⁵

¹¹ *Id.*

¹² 15 U.S.C. 78f(b)(5).

¹³ See, e.g., Securities Exchange Act Release Nos. 99238 (Dec. 26, 2023), 89 FR 113, 116 n.21 and accompanying text (Jan. 2, 2024) (SR–NYSE–2023–34) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1, Amending Sections 312.03(b) and 312.04 of the NYSE Listed Company Manual To Modify the Circumstances Under Which a Listed Company Must Obtain Shareholder Approval of a Sale of Securities Below the Minimum Price to a Substantial Security Holder of the Company); 100816 (Aug. 26, 2024), 89 FR 70674, 70677–78 nn.46–48 and accompanying text (Aug. 30, 2024) (SR–NASDAQ–2024–019) (Order Granting Approval of a Proposed Rule Change, to Rules 5605, 5615 and 5810 To Amend Phase-In Schedules for Certain Corporate Governance Requirements and Applicability of Certain Cure Periods).

¹⁴ See *id.*

¹⁵ The Commission has stated that the right of shareholders to vote at an annual meeting is an essential and important one. See, e.g., Securities Exchange Act Release Nos. 86406 (July 18, 2019), 84 FR 35431, 35432 (July 23, 2019) (SR–NYSE–2019–20) (Order Granting Approval of a Proposed Rule Change Amending Section 302 of the Listed Company Manual To Provide Exemptions for the

Among other things, annual shareholder meetings allow the shareholders of a company the opportunity to elect directors and meet with, and engage, management to discuss company affairs.¹⁶ The Commission has recognized that, in limited circumstances, the exchange requirement to hold an annual shareholder meeting may not be necessary for certain issuers of specific types of securities where the holders of such securities do not directly participate as equity holders or vote in the annual election of directors or generally on the operations or policies of the listed company.¹⁷ However, when approving a prior Exchange proposal for specific exemptions from the annual shareholder meeting requirement, which included an exemption for exchange-traded funds (“ETFs”), the Commission expressly stated that CEFs are still required to hold annual meetings under Section 302.00.¹⁸

The Exchange states in support of its current proposal that there are significant differences between listed CEFs and listed operating companies that justify also exempting listed CEFs from the Exchange’s annual meeting requirement.¹⁹ In particular, the Exchange states that there are significant statutory protections under the 1940 Act provided to the shareholders of CEFs,²⁰

Issuers of Certain Categories of Securities From the Obligation To Hold Annual Shareholders’ Meetings) (“NYSE Order”); 57268 (Feb. 4, 2008), 73 FR 7614, 7616 (Feb. 8, 2008) (SR–Amex–2006–31) (Order Approving Proposed Rule Change, as Modified by Amendment Nos. 1, 2, and 3 Thereto, Relating to Annual Shareholder Meeting Requirements) (“Amex Order”).

¹⁶ See, e.g., Amex Order at 7614; Securities Exchange Act Release No. 53578 (Mar. 30, 2006), 71 FR 17532 (Apr. 6, 2006) (SR–NASDAQ–2005–073) (Order Granting Approval of a Proposed Rule Change and Amendment Nos. 1 and 2 Thereto and Notice of Filing and Order Granting Accelerated Approval of Amendment No. 3 Thereto Relating to Rule 4350(e) To Amend the Annual Shareholder Meeting Requirement).

¹⁷ See NYSE Order at 35432; Amex Order at 7616. The Commission has also stated that where an exchange has exempted issuers of certain categories of securities from the exchange requirement to hold an annual meeting, such issuers would remain subject to any applicable state and federal securities laws that relate to annual meetings and may still be required to hold annual shareholder meetings in accordance with such state and federal securities laws. See *id.* In addition, such issuers would remain subject to state and federal securities laws that may require other types of shareholder meetings, such as special meetings of shareholders. See NYSE Order at 35432. The Commission has also stated that the exemptions apply only with respect to particular securities, and that if a company also lists other common stock or voting preferred stock, or their equivalent, such company must nevertheless hold an annual meeting for the holders of such securities during each fiscal year. See *id.* at 35433.

¹⁸ See NYSE Order at 35433 n.20. See also *infra* note 27.

¹⁹ See Notice, *supra* note 4, at 56447.

²⁰ See *id.* at 56448.

including requirements with respect to the election of directors by CEF shareholders,²¹ a requirement that directors who are not “interested persons”²² comprise at least 40% of the board,²³ requirements that certain specified material matters be approved by a majority of the directors who are not “interested persons,”²⁴ and requirements that certain specified material matters be approved by the shareholders.²⁵ The Exchange states that there are no parallel legal protections for the shareholders of public operating companies.²⁶ The Exchange also states that all of the categories of investment companies for which the Exchange has listing standards other than CEFs are already exempt from the annual shareholder meeting requirement of Section 302.00 (such exempted investment companies, “NYSE-Listed ETFs”).²⁷

The Commission received comments supporting the proposal.²⁸ Some commenters stated that Congress adopted the 1940 Act protections referenced by NYSE in lieu of an annual

shareholder meeting requirement.²⁹ Some commenters agreed with NYSE that 1940 Act requirements, such as those pertaining to director elections, directors who are not “interested persons,” and matters that require shareholder vote, protect CEF investors;³⁰ and some stated that the 1940 Act requirements rendered NYSE’s annual shareholder meeting requirement “superfluous.”³¹ Some commenters also claimed that certain investors exploit the current annual shareholder meeting requirement for their own gain—for example, by launching a proxy campaign to change a CEF’s management and/or investment strategy, to conduct tender offers, or to liquidate the CEF altogether.³² These commenters stated that annual meetings allow a minority investor to have an outsized influence over the CEF that results in harm to long-term retail investors in the CEF and disincentivizes the creation of new listed CEFs.³³ Some commenters also stated that annual shareholder meetings are costly to CEFs and that retail investor engagement at such meetings is limited, and concluded that the burden of the annual shareholder meeting requirement outweighs any potential benefits.³⁴

The Commission also received comments opposing the proposal.³⁵

Some commenters stated that the 1940 Act requirements referenced by the Exchange were adopted in addition to the Exchange’s pre-existing annual shareholder meeting requirement, rather than in lieu of it,³⁶ and some stated that the 1940 Act requirements are not a substitute for annual shareholder meetings.³⁷ Some commenters stated that CEFs are fundamentally different from other registered investment companies, including NYSE-Listed ETFs.³⁸ In particular, commenters stated that CEFs commonly trade at a discount to NAV,³⁹ and claimed that the inability of CEF investors to redeem shares at NAV makes CEF investors more vulnerable to actions by CEF management.⁴⁰ Commenters stated that, in light of these unique features of CEFs, annual meetings are an important tool to discipline CEF management.⁴¹ Commenters also stated that elimination of NYSE’s annual shareholder meeting requirement would harm CEF investors by reducing opportunities for shareholder activism (or the threat of such activism);⁴² further entrenching CEF management;⁴³ potentially increasing CEFs’ discounts to NAV;⁴⁴ and effectively disenfranchising CEF investors due to the infrequency with which shareholder meetings would be required under the 1940 Act⁴⁵ and the difficulty for shareholders to requisition special meetings.⁴⁶ Commenters also described other benefits of annual shareholder meetings to CEF investors, such as providing accountability,

²¹ See *id.* at 56447.

²² The term “interested person” is defined in Section 2(a)(19) of the 1940 Act, 15 U.S.C. 80a–2(a)(19).

²³ See Notice, *supra* note 4, at 56447.

²⁴ See *id.* at 56447–48.

²⁵ See *id.* at 56448.

²⁶ See *id.*

²⁷ See *id.* When justifying its prior proposal to exempt NYSE-Listed ETFs from the annual shareholder meeting requirement of Section 302.00, the Exchange stated, among other things, that the net asset value (“NAV”) of such products is determined by the market price of each fund’s underlying securities or other reference asset; and that because shareholders can value their investments in such products on an ongoing basis, the Exchange believes that there is less need for such shareholders to engage management at an annual meeting. See Securities Exchange Act Release No. 85889 (May 17, 2019), 84 FR 23815, 23816 (May 23, 2019) (SR–NYSE–2019–20) (Notice of Filing of Proposed Rule Change Amending Section 302 of the Listed Company Manual To Provide Exemptions for the Issuers of Certain Categories of Securities From the Obligation To Hold Annual Shareholders’ Meetings). See also NYSE Order at 35432.

²⁸ See, e.g., Letters from Paul G. Cellupica, General Counsel, and Kevin Ercole, Assistant General Counsel, Investment Company Institute, dated July 30, 2024 (“ICI Letter”); Investment Adviser Association, Securities Industry and Financial Markets Association (“SIFMA”), SIFMA’s Asset Management Group, and Insured Retirement Institute, dated July 30, 2024 (“SIFMA et al Letter”); Bruce Leto and Sara Crovitz, Stradley Ronon Stevens & Young, LLP, dated July 30, 2024 (“Stradley Ronon Letter”); Joseph V. Amato, President and Chief Investment Officer, Equities, Neuberger Berman Group LLC, dated July 30, 2024 (“Neuberger Berman Letter”); John McCann, Managing Director, Associate General Counsel, Teachers Insurance and Annuity Association of America (“TIAA”) and TIAA’s asset management affiliate Nuveen, LLC, dated July 30, 2024 (“TIAA Letter”); George F. Magera, General Counsel, Federated Hermes, Inc., dated July 31, 2024 (“Federated Hermes Letter”).

²⁹ See, e.g., ICI Letter at 7–9; SIFMA et al Letter at 2–3.

³⁰ See, e.g., ICI Letter at 9–13; Letter Type A at <https://www.sec.gov/comments/sr-nyse-2024-35/srnyse202435.htm>; Federated Hermes Letter at 1.

³¹ See, e.g., ICI Letter at 1 and 9; SIFMA et al Letter at 2; Stradley Ronon Letter at 3.

³² See, e.g., ICI Letter at 2–3, 17–24; Neuberger Berman Letter at 1–2; Federated Hermes Letter at 1–2; Stradley Ronon Letter at 1–2; TIAA Letter at 2.

³³ See, e.g., ICI Letter at 13–14; Neuberger Berman Letter at 1–2; Federated Hermes Letter at 1–2; Stradley Ronon Letter at 2; TIAA Letter at 2.

³⁴ See, e.g., ICI Letter at 14–15; Federated Hermes Letter at 2; Letter from George W. Morris, dated July 31, 2024.

³⁵ See, e.g., Letters from Paul N. Roth, Founding Partner Emeritus, Of Counsel, Schulte Roth & Zabel LLP, dated July 30, 2024 (“Schulte Letter”); Michael D’Angelo, Saba Capital Management, LP, dated July 30, 2024 (“Saba Letter”); Profs. Lucian A. Bebchuk, Harvard Law School, and Robert J. Jackson, Jr., NYU School of Law, dated July 30, 2024 (“Bebchuk & Jackson Letter”); Profs. Daniel J. Taylor, The Wharton School, Edwin Hu, UVA School of Law, Robert Bishop, Duke School of Law, Bradford Levy, Chicago Booth School of Business, Shiva Rajgopal, Columbia Business School, and Jonathan Zytznick, Georgetown University Law Center, on behalf of the Working Group on Market Efficiency and Investor Protection in Closed-End Funds, dated July 30, 2024 (“Working Group Letter”); Bryce A. Doty, Senior Portfolio Manager, Sit Investment Associates, dated July 29, 2024 (“Sit Letter”); Phillip Goldstein, Managing Partner, Bulldog Investors, LLP, dated July 30, 2024 (“Bulldog Letter”); Aaron T. Morris, Partner, Morris Kandinov, dated July 29, 2024 (“Morris Kandinov Letter”); John Y. Park, dated July 29, 2024 (“Park Letter”).

³⁶ See, e.g., Schulte Letter at 2; Bulldog Letter at 1–2.

³⁷ See, e.g., Morris Kandinov Letter at 2–6; Saba Letter at 8–9.

³⁸ See, e.g., Bebchuk & Jackson Letter at 5–7; Sit Letter at 1–2; Letter from Thomas DeCapo, dated July 29, 2024.

³⁹ See, e.g., Working Group Letter at 3; Schulte Letter at 4.

⁴⁰ See, e.g., Bebchuk & Jackson Letter at 5–6; Park Letter; Letters from 1607 Capital Partners, LLC, dated July 30, 2024 (“1607 Letter”); Jon Fenn, dated July 16, 2024.

⁴¹ See, e.g., Bebchuk & Jackson Letter at 7–8; Working Group Letter at 3; Letters from Ronald Mass, Chief Investment Officer, Almitas Capital, dated July 30, 2024, at 2; Andrew Gadlin, dated July 30, 2024.

⁴² A commenter stated that the current annual shareholder meeting mechanism has both a direct effect (e.g., replacing existing fund directors) and indirect effect (e.g., the fear of potential replacement gives incumbent CEF directors incentive to avoid underperformance altogether); and that approval of NYSE’s proposal would produce two types of entrenchment costs from the elimination of these direct and indirect effects. See Bebchuk & Jackson Letter at 7–8 and 10–11.

⁴³ See, e.g., Working Group Letter at 5.

⁴⁴ See, e.g., Working Group Letter at 6; Saba Letter at 1, 2, and 7 n.20; Sit Letter at 2.

⁴⁵ See, e.g., Sit Letter at 2–3; Bebchuk & Jackson Letter at 8–9.

⁴⁶ See, e.g., Working Group Letter at 5; Schulte Letter at 6–7 and n.28; Saba Letter at 2.

transparency, and a forum for shareholders to voice concerns;⁴⁷ and expressed concern with the removal of a right (required annual shareholder meetings) that shareholders may have relied upon when investing in CEFs.⁴⁸

The Commission has concerns about whether NYSE's proposal to exempt CEFs listed under Section 102.04A of the Manual from the annual shareholder meeting requirement set forth in Section 302.00 is designed to protect investors and the public interest, as required by Section 6(b)(5) of the Exchange Act.⁴⁹ Although the Commission previously approved a similar exemption for NYSE-Listed ETFs,⁵⁰ there are important differences between CEFs and ETFs. Shares of CEFs often trade at prices that are less than, or at a "discount" to, the funds' NAV per share. In contrast, while ETFs may trade at a discount, it is often to a much lesser degree than CEFs.⁵¹ Due to these circumstances, shareholders of CEFs may have an interest in expressing their views at annual shareholder meetings.

Moreover, the Commission has concerns with the sufficiency of the Exchange's analysis and whether the Exchange has met its burden to demonstrate that its proposal is consistent with the Exchange Act.⁵² The Exchange states that NYSE-Listed ETFs are already exempt from the annual shareholder meeting requirement of Section 302.00. However, the Exchange does not discuss or explain the

differences between NYSE-Listed ETFs and CEFs, which differences, as discussed above, may result in investor protection concerns for CEF shareholders with respect to eliminating the right to an annual shareholder meeting that may not be present for NYSE-Listed ETFs' shareholders. For example, the Exchange does not discuss whether the fact that CEF shares may trade at a large discount to NAV would raise any investor protection concerns with eliminating the annual shareholder meeting requirement. The Exchange also does not discuss the extent to which CEF investors participate in, and benefit from, annual shareholder meetings, such that eliminating the annual shareholder meeting requirement may raise investor protection concerns. In addition, while the Exchange discusses how certain requirements set forth in the 1940 Act are designed to protect CEF investors and the public interest, the Exchange does not discuss how its specific proposal to exempt CEFs from the Exchange's longstanding annual shareholder meeting requirement—and any resulting loss of benefits to CEF investors of annual shareholder meetings—would be designed to protect CEF investors and the public interest.

As a result, the Commission believes there are questions as to whether the proposal is consistent with Section 6(b)(5) of the Exchange Act⁵³ and its requirement, among other things, that the rules of a national securities exchange be designed to protect investors and the public interest. For this reason, it is appropriate to institute proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act⁵⁴ to determine whether the proposal should be approved or disapproved.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change is consistent with Section 6(b)(5) of the Exchange Act⁵⁵ or any other provision of the Exchange Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of

data, views, and arguments, the Commission will consider, pursuant to Rule 19b-4 under the Exchange Act,⁵⁶ any request for an opportunity to make an oral presentation.⁵⁷

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by October 31, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by November 14, 2024. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSE-2024-35 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-NYSE-2024-35. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public

⁴⁷ See, e.g., 1607 Letter; Letters from Andrew Park on behalf of the Americans for Financial Reform Education Fund, dated July 30, 2024, at 2-3; Michael Foster, dated July 16, 2024; James Gould, dated Aug. 6, 2024.

⁴⁸ See, e.g., Schulte Letter at 4; Saba Letter at 2; Bechuk & Jackson Letter at 12.

⁴⁹ 15 U.S.C. 78f(b)(5).

⁵⁰ See NYSE Order, *supra* note 15.

⁵¹ See Securities Act Release No. 10695, Investment Company Act Release No. 33646, S7-15-18 (Sept. 25, 2019), 84 FR 57162, 57165 (Oct. 24, 2019) (Exchange-Traded Funds Final Rule) ("The combination of the creation and redemption process with secondary market trading in ETF shares and underlying securities provides arbitrage opportunities that are designed to help keep the market price of ETF shares at or close to the NAV per share of the ETF."). See also *supra* note 27.

⁵² Under the Commission's Rules of Practice, the "burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change." 17 CFR 201.700(b)(3). The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding, and any failure of a self-regulatory organization to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the applicable rules and regulations. *Id.*

⁵³ 15 U.S.C. 78f(b)(5).

⁵⁴ 15 U.S.C. 78s(b)(2)(B).

⁵⁵ 15 U.S.C. 78f(b)(5).

⁵⁶ 17 CFR 240.19b-4.

⁵⁷ Section 19(b)(2) of the Exchange Act, as amended by the Securities Acts Amendments of 1975, Public Law 94-29 (June 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSE-2024-35 and should be submitted on or before October 31, 2024. Rebuttal comments should be submitted by November 14, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵⁸

J. Matthew DeLesDernier,
Deputy Secretary.

[FR Doc. 2024-23417 Filed 10-9-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101248; File No. SR-NYSE-2024-61]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

October 4, 2024.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (“Act”) ² and Rule 19b-4 thereunder, ³ notice is hereby given that on September 20, 2024, New York Stock Exchange LLC (“NYSE” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule (“Fee Schedule”) to delete the currently-filed “Optic Low Latency Circuit—1 Gb”

service as obsolete. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule (“Fee Schedule”) to delete the currently-filed “Optic Low Latency Circuit—1 Gb” service as obsolete.

In 2023, the Exchange filed to amend the Fee Schedule to add several “FIDS Circuits” available at the Mahwah, New Jersey data center (“MDC”), ⁴ including Optic Low Latency Circuits in 1 Gb, 10 Gb, and 40 Gb sizes. ⁵

Since that time, no Users ⁶ have opted to utilize the 1 Gb Optic Low Latency Circuit. Some market participants have informed the Exchange that the 1 Gb size of the Optic Low Latency Circuit is

⁴ Through its Fixed Income and Data Services (“FIDS”) (previously ICE Data Services) business, Intercontinental Exchange, Inc. (“ICE”) operates the MDC. The Exchange and NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc. and NYSE National, Inc. (together, the “Affiliate SROs”) are indirect subsidiaries of ICE.

⁵ See Securities Exchange Act Release No. 99165 (December 13, 2023), 88 FR 87832 (December 19, 2023) (SR-NYSE-2023-48).

⁶ For purposes of the Exchange’s colocation services, a “User” means any market participant that requests to receive colocation services directly from the Exchange. See Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR-NYSE-2015-40). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc. and NYSE National, Inc. (together, the “Affiliate SROs”). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. See SR-NYSEAMER-2024-59, SR-NYSEARCA-2024-81, SR-NYSECHX-2024-30, and SR-NYSEENAT-2024-27.

too small for their needs. Because there is no customer demand for the 1 Gb Optic Low Latency Circuit, the Exchange proposes to discontinue the service as obsolete.

General

The proposed changes would not apply differently to distinct types or sizes of market participants; rather, they would apply to all Users equally. As is currently the case, the Fee Schedule would be applied uniformly to all Users. The proposed changes are not intended to address any other issues and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act, ⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act, ⁸ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that discontinuing offering the 1 Gb Optic Low Latency Circuit would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Demand for the 1 Gb Optic Low Latency Circuit is non-existent and there are currently no customers that subscribe to the service. The Exchange does not expect demand to rebound given customers’ assessment that the 1 Gb-size of the circuit is too small for their needs. Removing references to the fees for this obsolete service from the Fee Schedule would make the Fee Schedule easier to read, understand, and administer.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would delete an obsolete service from the Fee Schedule,

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

⁵⁸ 17 CFR 200.30-3(a)(57).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

which would enhance transparency and alleviate potential customer confusion.

The Exchange believes that removing this obsolete service from the Fee Schedule would not permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed changes would apply equally to all Users: the obsolete 1 Gb Optic Low Latency Circuit would be removed for all customers.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.⁹ The proposed rule change is not designed to address any competitive issues but rather is designed to enhance the clarity and transparency of the Fee Schedule and alleviate possible customer confusion that may arise from the inclusion of obsolete services.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹²

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSE-2024-61 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to file number SR-NYSE-2024-61. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and

copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSE-2024-61 and should be submitted on or before October 31, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

J. Matthew DeLesDernier,
Deputy Secretary.

[FR Doc. 2024-23412 Filed 10-9-24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-101251; File No. SR-NYSECHX-2024-30]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

October 4, 2024.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 ("Act")² and Rule 19b-4 thereunder,³ notice is hereby given that, on September 20, 2024, the NYSE Chicago, Inc. ("NYSE Chicago" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule ("Fee Schedule") to delete the currently-filed "Optic Low Latency Circuit—1 Gb" service as obsolete. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

¹⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁹ 15 U.S.C. 78f(b)(8).

¹⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6)(iii). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹³ 15 U.S.C. 78s(b)(2)(B).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule ("Fee Schedule") to delete the currently-filed "Optic Low Latency Circuit—1 Gb" service as obsolete.

In 2023, the Exchange filed to amend the Fee Schedule to add several "FIDS Circuits" available at the Mahwah, New Jersey data center ("MDC"),⁴ including Optic Low Latency Circuits in 1 Gb, 10 Gb, and 40 Gb sizes.⁵

Since that time, no Users⁶ have opted to utilize the 1 Gb Optic Low Latency Circuit. Some market participants have informed the Exchange that the 1 Gb size of the Optic Low Latency Circuit is too small for their needs. Because there is no customer demand for the 1 Gb Optic Low Latency Circuit, the Exchange proposes to discontinue the service as obsolete.

⁴ Through its Fixed Income and Data Services ("FIDS") (previously ICE Data Services) business, Intercontinental Exchange, Inc. ("ICE") operates the MDC. The Exchange and New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc. and NYSE National, Inc. (together, the "Affiliate SROs") are indirect subsidiaries of ICE.

⁵ See Securities Exchange Act Release No. 99167 (December 14, 2023), 88 FR 88141 (December 20, 2023) (SR-NYSECHX-2023-24).

⁶ For purposes of the Exchange's colocation services, a "User" means any market participant that requests to receive colocation services directly from the Exchange. See Securities Exchange Act Release No. 87408 (October 28, 2019), 84 FR 58778 at n.6 (November 1, 2019) (SR-NYSECHX-2019-12). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Affiliate SROs. Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. See SR-NYSE-2024-61, SR-NYSEAMER-2024-59, SR-NYSEARCA-2024-81, and SR-NYSEENAT-2024-27.

General

The proposed changes would not apply differently to distinct types or sizes of market participants; rather, they would apply to all Users equally. As is currently the case, the Fee Schedule would be applied uniformly to all Users. The proposed changes are not intended to address any other issues and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁸ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that discontinuing offering the 1 Gb Optic Low Latency Circuit would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest. Demand for the 1 Gb Optic Low Latency Circuit is non-existent and there are currently no customers that subscribe to the service. The Exchange does not expect demand to rebound given customers' assessment that the 1 Gb-size of the circuit is too small for their needs. Removing references to the fees for this obsolete service from the Fee Schedule would make the Fee Schedule easier to read, understand, and administer.

The Exchange believes that the proposed rule change does not significantly affect the protection of investors or the public interest. The proposed rule change would delete an obsolete service from the Fee Schedule, which would enhance transparency and alleviate potential customer confusion.

The Exchange believes that removing this obsolete service from the Fee Schedule would not permit unfair discrimination between customers, issuers, brokers, or dealers. The

proposed changes would apply equally to all Users: the obsolete 1 Gb Optic Low Latency Circuit would be removed for all customers.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.⁹ The proposed rule change is not designed to address any competitive issues but rather is designed to enhance the clarity and transparency of the Fee Schedule and alleviate possible customer confusion that may arise from the inclusion of obsolete services.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹²

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of

⁹ 15 U.S.C. 78f(b)(8).

¹⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6)(iii). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) ¹³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR–NYSECHX–2024–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.
- All submissions should refer to file number SR–NYSECHX–2024–30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or

subject to copyright protection. All submissions should refer to file number SR–NYSECHX–2024–30 and should be submitted on or before October 31, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–23415 Filed 10–9–24; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20709 and #20710; TENNESSEE Disaster Number TN–20016]

Administrative Disaster Declaration of a Rural Area for the State of Tennessee

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative disaster declaration of a rural area for the State of Tennessee dated October 4, 2024.

DATES: Issued on October 4, 2024.

Physical Loan Application Deadline Date: December 3, 2024.

Economic Injury (EIDL) Loan Application Deadline Date: July 7, 2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, 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 of a rural area, applications for disaster loans may be submitted online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1–800–659–2955 for further assistance.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: May 8, 2024 through May 9, 2024.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Cannon, Giles, Maury, Sumner, Warren

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 20709C and for economic injury is 207100.

The State which received an EIDL Declaration is Tennessee.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,
Administrator.

[FR Doc. 2024–23496 Filed 10–9–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20703 and #20704; SOUTH CAROLINA Disaster Number SC–20012]

Presidential Declaration Amendment of a Major Disaster for the State of South Carolina

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of South Carolina (FEMA–4829–DR), dated September 29, 2024.

DATES: Issued on October 2, 2024.

Physical Loan Application Deadline Date: November 29, 2024.

Economic Injury (EIDL) Loan Application Deadline Date: June 30, 2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street

¹³ 15 U.S.C. 78s(b)(2)(B).

¹⁴ 17 CFR 200.30–3(a)(12).

SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of South Carolina, dated September 29, 2024, is hereby amended to include the following areas as adversely affected by the disaster:

Incident: Hurricane Helene.

Incident Period: September 25, 2024 and continuing.

Primary Counties (Physical Damage and Economic Injury Loans): Edgefield, Laurens, Union.

Contiguous Counties (Economic Injury Loans Only):

South Carolina: Chester.

Georgia: Columbia.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–23498 Filed 10–9–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20696 and #20697; VERMONT Disaster Number VT–20006]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Vermont

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Vermont (FEMA–4826–DR), dated September 26, 2024.

DATES: Issued on September 26, 2024.

Physical Loan Application Deadline Date: November 25, 2024.

Economic Injury (EIDL) Loan Application Deadline Date: June 26, 2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on September 26, 2024, Private Non-Profit organizations that provide essential

services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1–800–659–2955 for further assistance.

Incident: Severe Storms, Flooding, Landslides, and Mudslides.

Incident Period: July 29, 2024 through July 31, 2024.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Caledonia, Essex, Orleans.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere ...	3.250
<i>For Economic Injury:</i>	
Non-Profit Organizations without Credit Available Elsewhere ...	3.250

The number assigned to this disaster for physical damage is 206966 and for economic injury is 206970.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–23505 Filed 10–9–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20627 and #20628; KANSAS Disaster Number KS–20015]

Administrative Disaster Declaration of a Rural Area for the State of Kansas

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative disaster declaration of a rural area for the State of Kansas dated October 4, 2024.

DATES: Issued on October 4, 2024.

Physical Loan Application Deadline Date: December 3, 2024.

Economic Injury (EIDL) Loan Application Deadline Date: July 7, 2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT:

Alan Escobar, Office of Disaster Recovery & Resilience, 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 of a rural area, applications for disaster loans may be submitted online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1–800–659–2955 for further assistance.

Incident: Severe Storms, Straight-Line Winds, Tornadoes, and Flooding.

Incident Period: May 19, 2024.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Harvey

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere ...	5.375
Homeowners without Credit Available Elsewhere ...	2.688
Businesses with Credit Available Elsewhere ...	8.000
Businesses without Credit Available Elsewhere ...	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere ...	3.250
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere ...	4.000
Non-Profit Organizations without Credit Available Elsewhere ...	3.250

The number assigned to this disaster for physical damage is 20627C and for economic injury is 206280.

The State which received an EIDL Declaration is Kansas.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2024–23447 Filed 10–9–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20521 and #20522;
VERMONT Disaster Number VT-20002]

Presidential Declaration of a Major
Disaster for the State of Vermont

AGENCY: U.S. Small Business
Administration.
ACTION: Notice.

SUMMARY: This is a Notice of the
Presidential declaration of a major
disaster for the State of Vermont
(FEMA-4826-DR), dated September 26,
2024.

DATES: Issued on September 26, 2024.
Physical Loan Application Deadline
Date: November 25, 2024.
Economic Injury (EIDL) Loan
Application Deadline Date: June 26,
2025.

ADDRESSES: Visit the MySBA Loan
Portal at <https://lending.sba.gov> to
apply for a disaster assistance loan.
FOR FURTHER INFORMATION CONTACT:
Vanessa Morgan, Office of Disaster
Recovery & Resilience, U.S. Small
Business Administration, 409 3rd Street
SW, Suite 6050, Washington, DC 20416,
(202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is
hereby given that as a result of the
President's major disaster declaration on
September 26, 2024, applications for
disaster loans may be submitted online
using the MySBA Loan Portal <https://lending.sba.gov> or other locally
announced locations. Please contact the
SBA disaster assistance customer
service center by email at
disastercustomerservice@sba.gov or by
phone at 1-800-659-2955 for further
assistance.

Incident: Severe Storms, Flooding,
Landslides, and Mudslides.

Incident Period: July 29, 2024 through
July 31, 2024.

The following areas have been
determined to be adversely affected by
the disaster:

Primary Counties (Physical Damage and
Economic Injury Loans): Caledonia,
Essex, Orleans.

Contiguous Counties (Economic Injury
Loans Only):
Vermont: Franklin, Lamoille, Orange,
Washington.
New Hampshire: Coos, Grafton.
The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Avail- able Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688

	Percent
Businesses with Credit Avail- able Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations with- out Credit Available Else- where	3.250
For Economic Injury:	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations with- out Credit Available Else- where	3.250

The number assigned to this disaster
for physical damage is 205216 and for
economic injury is 205220.

(Catalog of Federal Domestic Assistance
Number 59008)

Rafaela Monchek,
Deputy Associate Administrator, Office of
Disaster Recovery & Resilience.
[FR Doc. 2024-23503 Filed 10-9-24; 8:45 am]
BILLING CODE 8026-09-P

DEPARTMENT OF STATE

[Public Notice: 12562]

International Security Advisory Board
(ISAB) Meeting Notice

ACTION: Closed meeting.

In accordance with section 10(a)(2) of
the Federal Advisory Committee Act, 5
U.S.C. 1009(a)(2), the Department of
State announces a meeting of the
International Security Advisory Board
(ISAB) to take place on October 30,
2024, at the Department of State,
Washington, DC.

Pursuant to section 10(d) of the
Federal Advisory Committee Act, 5
U.S.C. 1009(d), and 5 U.S.C. 552b(c)(1),
it has been determined that this Board
meeting will be closed to the public
because the Board will be reviewing and
discussing matters properly classified in
accordance with Executive Order 13526.
The purpose of the ISAB is to provide
the Department with a continuing
source of independent advice on all
aspects of arms control, disarmament,
nonproliferation, outer space, critical
infrastructure, cybersecurity, the
national security aspects of associated
technologies, international security, and
related aspects of public diplomacy. The
agenda for this meeting will include
classified discussions related to the
Board's ongoing studies on current U.S.
policy and issues regarding
biotechnology and military-civil fusion

strategy, multilateral disarmament
structures, and security cooperation and
arms transfers.

FOR FURTHER INFORMATION CONTACT: For
more information, contact Michelle
Dover, Executive Director of the
International Security Advisory Board,
Department of State, Washington, DC
20520, telephone: (202) 736-4930,
email: DoverME@state.gov.

Michelle E. Dover,
Executive Director, International Security
Advisory Board, Department of State.
[FR Doc. 2024-23419 Filed 10-9-24; 8:45 am]
BILLING CODE 4710-27-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA-2024-1448]

Agency Information Collection
Activities: Requests for Comments;
Clearance of a Renewed Approval of
Information Collection: Reporting of
Information Using Special
Airworthiness Information Bulletin

AGENCY: Federal Aviation
Administration (FAA), DOT.
ACTION: Notice and request for
comments.

SUMMARY: In accordance with the
Paperwork Reduction Act of 1995, the
FAA invites public comments about our
intention to request the Office of
Management and Budget (OMB)
approval to renew an information
collection. The Federal Register Notice
with a 60-day comment period soliciting
comments on the following collection of
information was published on July 23,
2024. The collection involves a
voluntary request for information on a
specific safety concern. The information
to be collected will be used to help the
FAA in an ongoing investigation to
determine the cause of a specific
condition, or whether the condition is
likely to exist or develop on other
aircraft, aircraft engines, propellers, or
appliances of the same type design.

DATES: Written comments should be
submitted by November 12, 2024.

ADDRESSES: Written comments and
recommendations for the proposed
information collection should be sent
within 30 days of publication of this
notice to www.reginfo.gov/public/do/PRAMain. Find this particular
information collection by selecting
"Currently under 30-day Review—Open
for Public Comments" or by using the
search function.

FOR FURTHER INFORMATION CONTACT:
Scott Wessley by email at:

scott.wessley@faa.gov; phone: 816–329–4148.

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.

OMB Control Number: 2120–0731.

Title: Reporting of Information Using Special Airworthiness Information Bulletin.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on July 23, 2024 (89 FR 59797). A special airworthiness information bulletin (SAIB) is an information tool that the FAA uses to alert, educate, and make recommendations to the aviation community about ways to improve the safety of a product. An SAIB contains non-regulatory, non-mandatory information and guidance for safety issues that do not meet the criteria for airworthiness directive (AD) action under title 14 of the Code of Federal Regulations (14 CFR) part 39. An SAIB may include recommended actions or inspections with a request for voluntary reporting of inspection results.

Respondents: Respondents may include mechanics, type clubs, owners, and operators of aircraft.

Frequency: Information is collected as needed to acquire additional information on a specific condition.

Estimated Average Burden per

Response: 5 minutes.

Estimated Total Annual Burden: 558 hours.

Issued on September 23, 2024.

Hollister B. Thorson,

Manager, Airworthiness Products Section, Operational Safety Branch, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–23449 Filed 10–9–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration**

[Docket No. FAA–2024–0433]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Commercial Air Tour Limitations in the Grand Canyon National Park Special Flight Rules Area

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 **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on February 15, 2024. The FAA will use the information it collects and reviews to monitor compliance with the regulations regarding air tours in the Grand Canyon National Park.

DATES: Written comments should be submitted by November 12, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Sandra L. Ray by email at: Sandra.ray@faa.gov; phone: 412–546–7344

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.

OMB Control Number: 2120–0653.

Title: Commercial Air Tour

Limitations in the Grand Canyon National Park Special Flight Rules Area.

Form Numbers: OMB 2120–0653.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period

soliciting comments on the following collection of information was published on February 15, 2024 (89 FR 11917). Each operator seeking to obtain or in possession of an air carrier operating certificate is mandated to comply with the requirements of 14 CFR part 135 or part 121, as appropriate. Thus, each of these operators conducting air tours in the Grand Canyon National Park is mandated to comply with the collection requirements for that airspace. The FAA will use the information it collects and reviews to evaluate compliance with the regulations and, if necessary, take enforcement action against violators of the regulations.

Respondents: 9.

Frequency: Quarterly.

Estimated Average Burden per

Response: Varies per Operator.

Estimated Total Annual Burden: 42 Hours.

Issued in Washington, DC, on October 7, 2024.

Sandra L. Ray,

Aviation Safety Inspector, AFS–260.

[FR Doc. 2024–23464 Filed 10–9–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration**

[Docket No. FAA–2024–1657]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Representatives of the Administrator, 14 CFR Part 183

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 **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 29, 2024. The collection involves the voluntary submission of application information for persons applying to become designated representatives of the FAA Administrator. The information to be collected will be used by the FAA to screen and select designees who will act as representatives of the FAA Administrator in performing various certification and examination functions

on behalf of the FAA. Additionally, the information will be used to determine if a designee continues to be qualified for the designation.

DATES: Written comments should be submitted by November 12, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Tanya Glines by email at: Tanya.glines@faa.gov; phone: 202-380-5896.

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.

OMB Control Number: 2120-0033.

Title: Representatives of the Administrator, 14 CFR part 183.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 29, 2024 (89 FR 46571). Title 49, United States Code, Section 44702 states that the Secretary of Transportation may delegate to any properly qualified private person, the examination and testing necessary for the issuance of certificates under Title VI of the Federal Aviation Act. Title 14, Code of Federal Regulations (14 CFR), part 183, Representatives of the Administrator, describes the requirements for delegating to any properly qualified private person, the examination and testing necessary for the issuance of airmen certificates.

Response to this collection of information is required to obtain a benefit, specifically, to obtain a FAA designation as a representative of the FAA Administrator. Designee applicants come from private industry. They are experts in the aviation and medical communities who are familiar with the regulations and certification requirements necessary to issue an FAA certificate. Only highly experienced

aviation professionals are expected to respond to the collection. The collection is for reporting of an individual's eligibility and qualifications and occurs on an as needed basis for initial applicants. However, if an individual is not selected as a designee, their application must be updated whenever information changes (as needed) and at least every 12 calendar months (annually). The FAA has now fully implemented the use of the Designee Management System (DMS) web-based application, located at <https://designee.faa.gov/#/login>, for the application process for all designee types.

Additionally, designees must report any arrest, indictment, or conviction for violation of local, State, or Federal law to the FAA within 30 days of such arrest, indictment, or conviction.

Respondents: Approximately 2,200 individual designee applicants and designated representatives of the FAA Administrator.

Frequency: As needed, annually.

Estimated Average Burden per

Response: 3 hours.

Estimated Total Annual Burden: 5,000 hours.

Issued in Washington, DC, on October 7, 2024.

Tanya A. Glines,

Aviation Safety Inspector, FAA Office of Safety Standards, Aircraft Maintenance Division, Airmen Section.

[FR Doc. 2024-23450 Filed 10-9-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2023-0055; Notice 2]

Blue Bird Body Company, Denial of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Denial of petition.

SUMMARY: Blue Bird Body Company (Blue Bird) has determined that certain model year (MY) 2019–2024 Blue Bird Vision and MY 2020–2024 Blue Bird All American school buses do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 217, *Bus Emergency Exits and Window Retention and Release*. Blue Bird filed two noncompliance reports, both dated August 9, 2023, and subsequently petitioned NHTSA (the "Agency") on September 13, 2023, for a decision that the subject noncompliance is

inconsequential as it relates to motor vehicle safety. This document announces the denial of Blue Bird's petition.

FOR FURTHER INFORMATION CONTACT: Daniel Lind, General Engineer, NHTSA, Office of Vehicle Safety Compliance, (202) 366-7235.

SUPPLEMENTARY INFORMATION:

I. Overview

Blue Bird determined that certain MY 2019–2024 Blue Bird Vision and MY 2020–2024 Blue Bird All American school buses do not fully comply with paragraph S5.5.3(b) of FMVSS No. 217, *Bus Emergency Exits and Window Retention and Release* (49 CFR 571.217).

Blue Bird filed two noncompliance reports, both dated August 9, 2023, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. Blue Bird petitioned NHTSA on September 13, 2023, for an exemption from the notification and remedy requirements of 49 U.S.C. chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

Notice of receipt of Blue Bird's petition was published with a 30-day public comment period, on December 6, 2023, in the **Federal Register** (88 FR 84872). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Then follow the online search instructions to locate docket number "NHTSA-2023-0055."

II. Vehicles Involved

Approximately 28,765 MY 2019–2024 Blue Bird Vision and 403 MY 2020–2024 Blue Bird All American school buses, manufactured between July 1, 2019, and August 3, 2023, were reported by the manufacturer.

III. Noncompliance

Blue Bird explains that the Emergency Exit Label in the subject vehicles contains lettering that does not meet the lettering height required by paragraph S5.5.3(b) of FMVSS No. 217. Specifically, the lettering height was 0.882 centimeters and therefore does not meet the minimum lettering height requirement of 1 centimeter.

IV. Rule Requirements

Paragraph S5.5.3(b) of FMVSS No. 217 includes the requirements relevant

to this petition. Concise operating instructions describing the motions necessary to unlatch and open the emergency exit shall be located within 15 centimeters of the release mechanism on the inside surface of the bus. These instructions shall be in letters at least 1 centimeter high and of a color that contrasts with its background.

V. Summary of Blue Bird's Petition

The following views and arguments presented in this section, "V. Summary of Blue Bird's Petition," are the views and arguments provided by Blue Bird. They do not reflect the views of the Agency. Blue Bird describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

Blue Bird contends that the subject noncompliance is inconsequential to motor vehicle safety because the difference between 1 centimeter and 0.882 centimeters would be difficult to differentiate without the use of precise measuring equipment. A 0.118 centimeter difference is less than 3/64ths of an inch or 0.047 inches, which Blue Bird argues would be unrecognizable and would not cause the instructions to be unclear to passengers or impact their ability to open the door in an emergency.

In 2022, NHTSA denied a petition by Collins Bus Corporation (Collins) in which the lettering height on the affected buses was 2 millimeters less than 1 centimeter. Collins contended that some of the lettering in the labeled message exceeds the requirement by 1 millimeter. Therefore, the difference of the noncompliant lettering being 2 millimeters smaller than required should be deemed inconsequential. However, Blue Bird notes that NHTSA was not persuaded by Collins's assertion that a 2 millimeter measurement is any less significant than a 1 millimeter measurement. Blue Bird says that NHTSA's decision in this case implies that a 0.118 centimeter variation from the required lettering height at a single location can be considered inconsequential.

Moreover, Blue Bird believes that Vernier caliper jaws, when used for the official measurement of letter height can introduce inaccuracies, particularly in discerning small variations from the required height. Blue Bird says manual error in the repeatability of both the measurement device and the user could lead to discrepancies that exceed the difference between the Blue Bird text size from the requirement. Blue Bird contends that the photo provided of the measurement in this case illustrates the potential for human error in identifying

a small variation. According to Blue Bird, "the caliper is not positioned flat against the decal, and only one location on the decal was measured." Therefore, Blue Bird believes that a discrepancy of 0.118 centimeters could be attributed to a slight angle of the calipers or measurements conducted at various points on the signage.

According to Blue Bird, its lettering meets all other FMVSS No. 217 labeling requirements, specifically that (1) operating instructions must be "concise" and describe "the motions necessary to unlatch and open the emergency exit," (2) operating instructions must "be located within 15 centimeters of the release mechanism on the inside surface of the bus," and (3) operating instructions must be "of a color that contrasts with [their] background."

Blue Bird asserts NHTSA has not put forth any claim or reasoning indicating that a 0.118 centimeter variation from the 1 centimeter lettering height requirement "compromises a passenger's ability to safely view or understand the lettering." Furthermore, Blue Bird contends that NHTSA's prior determination on the Collins petition notes the substantial difference between a 1 millimeter and a 2 millimeter variation from the requirement. Additionally, Blue Bird believes it has effectively demonstrated that the manual use of Vernier calipers can introduce "discrepancies and variations when distinguishing variations as small as 0.118 cm."

Blue Bird concludes by stating its belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety and its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

VI. NHTSA's Analysis

A. General Principles

Congress passed the National Traffic and Motor Vehicle Safety Act of 1966 (the Safety Act) with the express purpose of reducing motor vehicle accidents, deaths, injuries, and property damage. *See* 49 U.S.C. 30101. To this end, the Safety Act empowers the Secretary of Transportation to establish and enforce mandatory Federal Motor Vehicle Safety Standards (FMVSS). *See* 49 U.S.C. 30111. The Secretary has delegated this authority to NHTSA. *See* 49 CFR 1.95.

NHTSA adopts a FMVSS only after the Agency has determined that the requirements are objective and

practicable and meet the need for motor vehicle safety. *See* 49 U.S.C. 30111(a). Thus, there is a general presumption that the failure of a motor vehicle or item of motor vehicle equipment to comply with a FMVSS increases the risk to motor vehicle safety beyond the level deemed appropriate by NHTSA through the rulemaking process. To protect the public from such risks, manufacturers whose products fail to comply with a FMVSS are normally required to conduct a safety recall under which they must notify owners, purchasers, and dealers of the noncompliance and provide a free remedy. *See* 49 U.S.C. 30118–30120. However, Congress has recognized that, under some limited circumstances, a noncompliance could be "inconsequential" to motor vehicle safety. It therefore established a procedure under which NHTSA may consider whether it is appropriate to exempt a manufacturer from its notification and remedy (*i.e.*, recall) obligations. *See* 49 U.S.C. 30118(d), 30120(h). The Agency's regulations governing the filing and consideration of petitions for inconsequentiality exemptions are set out at 49 CFR part 556.

Under the Safety Act and Part 556, inconsequentiality exemptions may be granted only in response to a petition from a manufacturer, and then only after notice in the **Federal Register** and an opportunity for interested members of the public to present information, views, and arguments on the petition. In addition to considering public comments, the Agency will draw upon its own understanding of safety-related systems and its experience in deciding the merits of a petition. An absence of opposing argument and data from the public does not require NHTSA to grant a manufacturer's petition.

Neither the Safety Act nor part 556 define the term "inconsequential." Rather, the Agency determines whether a particular noncompliance is inconsequential to motor vehicle safety based upon the specific facts before it in a particular petition. An important issue to consider in determining inconsequentiality based upon NHTSA's prior decisions on noncompliance issues was the safety risk to individuals who experience the type of event against which the recall would otherwise protect.¹ NHTSA also

¹ *See Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of*

does not consider the absence of complaints or injuries when determining whether a noncompliance is inconsequential to safety. The Safety Act is preventive, and manufacturers cannot and should not wait for deaths or injuries to occur in their vehicles before they carry out a recall. *See, e.g., United States v. Gen. Motors Corp.*, 565 F.2d 754, 759 (D.C. Cir. 1977). Indeed, the very purpose of a recall is to protect individuals from risk. *See id.* “Most importantly, the absence of a complaint does not mean there have not been any safety issues, nor does it mean that there will not be safety issues in the future.”² “[T]he fact that in past reported cases good luck and swift reaction have prevented many serious injuries does not mean that good luck will continue to work.”³ Rather, the issue to consider is the consequence to an occupant who is exposed to the consequence of that noncompliance.⁴

Further, because each inconsequential noncompliance petition must be evaluated on its own facts and determinations are highly fact-dependent, NHTSA does not consider prior determinations as binding precedent. Petitioners are reminded that they have the burden of persuading NHTSA that the noncompliance is inconsequential to safety.

B. Response to Blue Bird's Arguments

NHTSA reviewed Blue Bird's arguments that the subject noncompliance is inconsequential to motor vehicle safety. Blue Bird contends that the lettering height of the operating instructions describing the motions necessary to unlatch and open the emergency window exit failing to meet the Emergency Exit Identification requirements, as specified in paragraph S5.5.3(b) of FMVSS No. 217, poses little, if any, risk to motor vehicle safety. NHTSA does not agree.

Petition for Decision of Inconsequential Noncompliance, 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

² *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance*, 81 FR 21663, 21666 (Apr. 12, 2016).

³ *United States v. Gen. Motors Corp.*, 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it “results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future”).

⁴ *See Gen. Motors Corp.; Ruling on Petition for Determination of Inconsequential Noncompliance*, 69 FR 19897, 19900 (Apr. 14, 2004); *Cosco, Inc.; Denial of Application for Decision of Inconsequential Noncompliance*, 64 FR 29408, 29409 (June 1, 1999).

The purpose of FMVSS No. 217 is to minimize the likelihood of occupants being thrown from the bus and to provide a means of readily accessible emergency egress (*See* 49 CFR 571.217 S2). The Emergency Exit Identification requirements at S5.5.3(b) of FMVSS No. 217, at issue here, are specific to the operating instructions required for emergency exits in school buses. Blue Bird argues that the 0.882 centimeter letter height shortfall of its operating instructions is “not significant enough to make the instructions unclear to passengers or compromise their ability to open the door in an emergency.” Blue Bird states “A 0.118 cm difference is less than 3/64ths of an inch or 0.047 inches and will be unrecognizable.” However, Blue Bird provides no evidence demonstrating that the difference in letter height present in this noncompliance does not affect readability of the operating instructions. NHTSA also does not find merit in Blue Bird's statement that “NHTSA has not provided any claim or reasoning that that 0.118 cm variation from the 1 cm lettering height requirement compromises a passenger's ability to safely view or understand the lettering” because the burden of persuasion lies with Blue Bird to provide evidence to support its petition. NHTSA adoption of the 1 cm requirement when issuing the FMVSS was based on the statutory requirement that the FMVSS meets the need for motor vehicle safety. However, Blue Bird failed to provide evidence in support of its claim that a deviation from that requirement is inconsequential to safety. Consequently, NHTSA is not persuaded by Blue Bird's argument that the readability of the operating instructions is unaffected by its noncompliance with the letter height requirement.

Regarding Blue Bird's argument that the letter height variation of 0.118 centimeters is inconsequential based on previous NHTSA decisions,⁵ NHTSA does not agree with Blue Bird that NHTSA's denial of the Collins petition referenced by Blue Bird warrants granting this petition. NHTSA does not agree with Blue Bird that “NHTSA's decision [to deny the petition] suggests that a mere 0.118 cm variation from the standard measured in a single location *can* be deemed inconsequential,” as NHTSA made no such statement in its denial of the Collins petition. NHTSA also does not agree with Blue Bird that “NHTSA expressly noted [in the previous petition] that there *is* a *material* difference in a 1 mm variation

versus a 2 mm variation,” as NHTSA made no such statement in the denial of the Collins petition. Furthermore, NHTSA does not agree that NHTSA's analysis in its denial of the Collins petition supports granting Blue Bird's petition here, for three reasons. First, NHTSA specifically stated in the denial of the Collins petition that “[e]mergency egress occurs under states of emergency, which may include fire, smoke, panicked children, etc. As such, the dilution of these emergency egress marking requirements in school buses is consequential to motor vehicle safety.” Blue Bird did not provide any evidence to demonstrate that a smaller letter height is inconsequential to emergency egress under states of emergency. Second, NHTSA specifically stated in the denial of the Collins petition that “NHTSA is not persuaded by Collins's argument that the readability of the operating instructions is unaffected by the noncompliance with the letter height requirement, as no evidence was provided in support of this claim.” Blue Bird also did not provide any evidence to demonstrate that the readability of the operating instructions is unaffected by the noncompliance with the letter height requirement. Third, NHTSA specifically stated in the denial of the Collins petition that “NHTSA is not persuaded by Collins's argument that a 2 mm measurement is any less substantial than a 1 mm measurement, as no evidence was provided in support of this claim.”⁶ Blue Bird also did not provide any evidence to demonstrate that a 0.118 centimeter difference in letter height is not substantial with respect to readability of emergency exit operating instructions. Consequently, NHTSA is not persuaded by Blue Bird's argument that the letter height variation of 0.118 cm is inconsequential, as no evidence was provided in support of this claim.

NHTSA is also not persuaded by Blue Bird's argument that “the jaws of a Vernier caliper when used for the official measurement of letter height can be inaccurate and inconsistent when used to differentiate such small variation from the standard.” Blue Bird states that “[m]annual error in repeatability of the measurement device and user could result in differences that exceed the difference the Blue Bird text size is from the requirement A difference of .118 cm could easily be accounted for by a slight angle of the calipers or measurements taken in

⁵ Blue Bird only cited one previous NHTSA decision, which is the Collins petition.

⁶ NHTSA's statement was a direct response to Collins stating that a 1 millimeter difference was “substantial,” but a 2 millimeter difference was “inconsequential.”

multiple locations on the signage.” However, Blue Bird did not provide any evidence to demonstrate the ease by which such manual errors could occur. NHTSA also does not agree with Blue Bird that “Blue Bird has demonstrated that manual use of Vernier calipers can create discrepancies and variations when distinguishing variations as small as .118 cm,” as no such demonstrations were provided as part of Blue Bird’s petition. Consequently, NHTSA is not persuaded by Blue Bird’s argument that Vernier calipers can be inaccurate and inconsistent for the measurement of label letter heights, as no evidence was provided in support of this claim. Arguments about how the lettering height is measured are also not relevant given that Blue Bird has acknowledged its lettering height actually did not meet the minimum lettering height requirement of the standard.

Regarding the additional requirements at S5.5.3(b) of FMVSS No. 217 for the operating instructions, NHTSA agrees with Blue Bird that the operating instructions “lettering meets all other labeling requirements” at S5.5.3(b) of FMVSS No. 217, but NHTSA does not agree with Blue Bird that partial compliance with FMVSS No. 217 is sufficient to render the partial noncompliance inconsequential to safety. NHTSA is not persuaded by Blue Bird’s argument that meeting the other requirements within S5.5.3(b) of FMVSS No. 217 for the operating instructions mitigates Blue Bird’s noncompliance with the letter height requirement, as no evidence was provided in support of this claim.

VII. NHTSA’s Decision

In consideration of the foregoing, NHTSA has decided that Blue Bird has

not met its burden of persuasion that the subject FMVSS No. 217 noncompliance is inconsequential to motor vehicle safety. Accordingly, Blue Bird’s petition is hereby denied and Blue Bird is consequently obligated to provide notification of and free remedy for that noncompliance under 49 U.S.C. 30118 and 30120.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8)

Eileen Sullivan,

Associate Administrator for Enforcement.

[FR Doc. 2024–23460 Filed 10–9–24; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for New Special Permits

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

ACTION: List of applications for special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation’s Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before November 12, 2024.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety

Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT:

Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Each mode of transportation for which a particular special permit is requested is indicated by a number in the “Nature of Application” portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

Copies of the applications are available for inspection in the Records Center, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on October 1, 2024.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21856–N	Lynden Air Cargo, LLC	172.101(j)	To authorize the transportation in commerce of certain cryogenic liquids by air in quantities that exceed the limits specified in Column 9B of the 172.101 Hazardous Materials Table. (mode 4)
21857–N	Trinity Industries, Inc	172.203(a), 173.319, 179.401–1	To authorize the manufacture, mark, sale, and use of DOT specification 113A90W tank cars for the transportation of certain non-flammable cryogenic liquids. (mode 2)
21859–N	Plastipak Packaging, Inc	178.33b–5(a), 178.33b–6(a)	To authorize the manufacture, mark, sale, and use of non-DOT specification plastic non-refillable inside containers conforming with all regulations applicable to a DOT specification 2S plastic inside container, except that recycled plastic may be used, for the transportation in commerce of the hazardous materials in paragraph 6. (modes 1, 2, 3, 4, 5)
21863–N	Munro & Associates, Inc	173.185(f)	To authorize the transportation in commerce of a damaged lithium ion battery. (mode 1)

SPECIAL PERMITS DATA—Continued

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21864–N	Arrowhead Industrial Services (U.S.A.), Inc.	172.203(a), 172.301(c), 173.301(a), 173.301(f)(1).	To authorize the transportation in commerce of certain DOT specification cylinders, UN/ISO pressure vessels, or pressure vessels constructed to Internationally recognized standards as listed in Table 1 of Arrowhead Transportation SOP, AISI–TransportSP–000 containing Division 2.1 or 2.2 materials for the purpose of performing certain qualification tests that cannot be performed at their current location. (mode 1)
21865–N	Chemstream, Inc	172.102(c)(3)	To authorize the use of MC 312 or DOT 412 cargo tank fitted with venting and a pressure relief device for the transportation in commerce of hydrogen peroxide. (mode 1)
21866–N	Electronic Recyclers International Inc.	172.700(a), 172.400, 172.200, 172.300, 172.102(c)(2), 173.159a(c)(2), 173.185(c)(1)(iii), 173.185(c)(1)(iv), 173.185(c)(1)(v), 173.185(c)(3), 173.185(f).	To authorize the transportation in commerce of DDR and end of life batteries and to allow various chemistries in the same alternative packaging. (mode 1)
21867–N	Oxyde Chemicals, Inc	171.22(c), 173.241, 173.241(c) ..	To authorize the use of non-DOT specification bulk packaging (Flexitank) fitted inside an intermodal container for the transportation of specified materials by motor vehicle, specifically to deliver the container to the port of lading to board a container ship for export. (modes 1, 3)
21869–N	Van Troxel International Inc ..	Part 172 Subparts C, D, E, and F, 173.302a(a)(1), 173.304a(a)(1).	To authorize the transportation in commerce of non-compliant inner containers that have not been appropriately marked. (mode 1)
21870–N	Air Transport International, Inc.	172.101(j), 173.27(b)	To authorize the transportation in commerce of cesium by passenger-carrying aircraft which is forbidden for transport aboard passenger-carrying aircraft per Column 9A of the 172.101 HMR. (mode 5)

[FR Doc. 2024–23407 Filed 10–9–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Actions on Special Permits

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

ACTION: Notice of actions on special permit applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of

Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before November 12, 2024.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline

and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on October 1, 2024.

Donald P. Burger,
Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA—GRANTED

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
16118–M	Toyota Motor Sales USA Inc	173.301(a)(1)	To modify the special permit to align with the provisions in the UN Model Regulations, Special Provision 392.
21547–M	Mazda Motor of America, Inc	172.101(j)	To modify the special permit to authorize an additional lithium battery.
21683–N	Colep Packaging Portugal, S.A.	178.33–7(a), 178.33a–7(a)	To authorize the manufacture, mark, sale, and use of non-DOT specification receptacles with reduced wall thickness.

SPECIAL PERMITS DATA—GRANTED—Continued

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21731-N	Inversion Space Company	173.185(b), 173.62(c), 177.848(b).	To authorize the transportation in commerce of certain hazardous materials in non-DOT specification packaging (spacecraft) and limited quantities of Division 1.4S and 1.4C explosives secured within the spacecraft.
21737-N	Remolques Tanques y Equipos, S.A. DE C.V.	178.345-2	To authorize the manufacture, mark, sale, and use of DOT 406, 407, and 412 specification cargo tanks using alternative materials of construction.
21790-N	Seattle Children's Hospital	173.199, 178.609(d)	To authorize the transportation in commerce of live mice infected with Mycobacterium tuberculosis (a Category B infectious substance).
21799-N	Nebraska Central Railroad Company.	172.203(a), 174.24(a), 174.24(b), 174.24, 174.26(a), 174.26(b), 174.26.	To authorize the use of electronic means to maintain and communicate on board train consist information in lieu of paper documentation when hazardous materials are transported by rail.
21808-N	Albedo Space Corp	173.301(f)(1)	To authorize the transportation in commerce of spacecraft containing specification cylinders that are not equipped with pressure relief devices.
21829-N	Tatonduk Outfitters Limited ...	172.101(j)(2), 173.242, 173.27 ...	To authorize the transportation in commerce of certain Class 3 hazardous materials in non-DOT specification bulk packaging aboard cargo-only aircraft.
21830-N	Everts Air Fuel, Inc	172.101(j), 173.242, 173.27	To authorize the transportation in commerce of certain Class 3 hazardous materials in non-DOT specification bulk packaging aboard cargo-only aircraft.
21839-N	Kraken Power GmbH	172.101(j)	To authorize the transportation in commerce of lithium ion batteries exceeding 35 kg aboard cargo-only aircraft.
21845-N	Polyventive LLC	172.506(a), 172.506(a)(1), 172.101(e), 173.241(d).	To authorize the one-time, one-way transportation of a leaking container for the purpose of repacking.
21850-N	Reflex Aerospace GmbH	173.185(a)	To authorize the transportation in commerce of prototype lithium ion batteries contained in equipment by cargo-only aircraft.
21860-N	Veolia ES Technical Solutions LLC.	173.21(b), 173.51, 173.54(a), 173.56(b).	To authorize the one-time, one-way transportation in commerce of unapproved explosives for final destruction.

SPECIAL PERMITS DATA—DENIED

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
15773-M	Roche Molecular Systems, Inc.	173.242(e)(1)	To modify the special permit to remove the requirement that the special permit accompany the shipment.
21352-N	Veolia North America Regeneration Services, LLC.	173.244(a)(2), 173.31(e)(2)(ii), 179.22(e).	To authorize the transportation in commerce of certain PIH materials in 105J500W specification tank cars that were originally manufactured prior to March 16, 2009, and have been modified to meet the current specification requirements for DOT 105H500W tank cars.
21832-N	Larosa Enterprise, LLC	173.306(a)(1)	To authorize the transportation in commerce of butane as limited quantities when the capacity of the receptacle exceeds four fluid ounces.

SPECIAL PERMITS DATA—WITHDRAWN

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21611-N	Cenergy Solutions Inc	172.101(a), 173.302	To authorize the use of MMC-331 vessels for the transportation of adsorbed methane by highway.
21678-M	Moxion Power Co	172.102(c)(1)	To modify the special permit to authorize international transportation aboard aircraft.
21809-N	Bhiwadi Cylinders Private Limited.	173.304a(a)(1)	To authorize the manufacture, mark, sale, and use of non-specification inner containers similar to specification DOT 2Q inner containers.
21821-N	Sandvik, Inc	172.101(j)	To authorize the transportation in commerce of lithium ion batteries exceeding 35kg by cargo-only aircraft.
21841-N	General Dynamics Land Systems Edgefield Test Center.	172.204(c)(3), 172.101(k)(9), 173.27(b)(2), 173.27(b)(3).	To authorize the transportation of UN0328 and UN0417 which are forbidden by cargo-only aircraft by cargo-only aircraft.

[FR Doc. 2024-23406 Filed 10-9-24; 8:45 am]

BILLING CODE 4910-60-P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA-2024-0137]

Pipeline Safety: Information Collection Activities

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

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, PHMSA invites public comments about PHMSA's intention to request Office of Management and Budget (OMB) approval to renew eight information collections that are scheduled to expire in 2025. PHMSA has reviewed each information collection and considers them vital to maintaining pipeline safety. As such, PHMSA will request renewal from OMB, without change, for each information collection.

DATES: Interested persons are invited to submit comments on or before December 9, 2024.

ADDRESSES: Comments may be submitted in the following ways:

E-Gov Website: <http://www.regulations.gov>. This site allows the public to submit comments on any Federal Register notice issued by any agency.

Fax: 1-202-493-2251.

Mail: Docket Management Facility; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590-0001.

Hand Delivery: Room W12-140 on the ground level of DOT, West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m. ET, Monday through Friday, except Federal holidays.

Instructions: Identify the docket number, PHMSA-2024-0137, at the beginning of your comments. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. You should know that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). Therefore, you may want to review

DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, (65 FR 19477) or visit <http://www.regulations.gov> before submitting any such comments.

Docket: For access to the docket or to read background documents or comments, go to <http://www.regulations.gov> at any time or to Room W12-140 on the ground level of DOT, West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m. ET, Monday through Friday, except Federal holidays. If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: "Comments on: PHMSA-2024-0137." The Docket Clerk will date stamp the postcard prior to returning it to you via the U.S. mail. Please note that due to delays in the delivery of U.S. mail to Federal offices in Washington, DC, we recommend that persons consider an alternative method (internet, fax, or professional delivery service) of submitting comments to the docket and ensuring their timely receipt at DOT.

Privacy Act Statement: DOT may solicit comments from the public regarding certain general notices. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this notice 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 notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 CFR 190.343, you may ask PHMSA to give confidential treatment to information you give to the Agency by taking the following steps: (1) mark each page of the original document submission containing CBI as "Confidential"; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the

FOIA, and they will not be placed in the public docket of this notice.

Submissions containing CBI should be sent to Angela Hill, DOT, PHMSA, 1200 New Jersey Avenue SE, PHP-30, Washington, DC 20590-0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT:

Angela Hill by telephone at 202-366-1246 or by email at Angela.Hill@dot.gov.

SUPPLEMENTARY INFORMATION: Title 5, Code of Federal Regulations (CFR) section 1320.8(d), requires PHMSA to provide interested members of the public and affected agencies the opportunity to comment on information collection and recordkeeping requests before they are submitted to OMB for approval. This notice identifies eight information collection requests that PHMSA will submit to OMB for renewal and requests comment from interested parties. The information collections (including their expiration dates) are as follows: (1) OMB control number 2137-0627, OPID Assignment Request and Registry Notifications (03/31/2025); (2) OMB control number 2137-0600, Qualification of Pipeline Safety Training (04/30/2025); (3) OMB control number 2137-0605, Hazardous Liquid Integrity Management (04/30/2025); (4) OMB control number 2137-0622, Public Awareness Program (04/30/2025); (5) OMB control number 2137-0584, Gas and Liquid Pipeline Safety Program Certification (05/31/2025); (6) OMB control number 2137-0589, Response Plans for Onshore Oil Pipelines (9/30/2025); (7) OMB control number 2137-0610, Gas Transmission Integrity Management in HCAs (09/30/2025); and (8) OMB 2137-0624, Control Room Management/Human Factors (09/30/2025).

The following information is provided for these information collections: (1) Title of the information collection; (2) OMB control number; (3) Current expiration date; (4) Type of request; (5) Abstract of the information collection activity; (6) Description of affected public; (7) Estimate of total annual reporting and recordkeeping burden; and (8) Frequency of collection.

PHMSA will request a three-year term of approval for each of the following information collection activities. PHMSA requests comments on the following information:

1. *Title:* OPID Assignment Request and Registry Notifications.

OMB Control Number: 2137-0627.

Current Expiration Date: 3/31/2025.

Type of Request: Renewal with no change of a currently approved collection.

Abstract: The National Registry of Pipeline and LNG Operators serves as the storehouse for the reporting requirements for an operator regulated or subject to reporting requirements under 49 CFR parts 192, 193, or 195. This mandatory information collection would require jurisdictional pipeline operators to submit the required data to register with the National Registry of Pipeline and LNG Operators and notify PHMSA when they experience significant asset changes, including new construction, that affect PHMSA's ability to accurately monitor and assess pipeline safety performance. Certain types of changes to, or within, an operator's facilities or pipeline network represent potential safety-altering activities for which PHMSA may need to inspect, investigate, or otherwise oversee to ensure that any public safety concerns are adequately and proactively addressed. The forms for assigning and maintaining Operator Identification (OPID) information are the Operator Assignment Request Form (PHMSA F 1000.1) and Operator Registry Notification Form (PHMSA F 1000.2). The purpose of this information collection is to maintain an accurate assessment of the nation's pipeline infrastructure and to be kept abreast of conditions that could potentially compromise the safety and economic viability of the U.S. pipeline system. Due to the provisions contained within the Safety of Gas Gathering Pipelines: Extension of Reporting Requirements, Regulation of Large, High-Pressure Lines, and Other Related Amendments final rule, gas gathering pipeline operators must now request OPIDs due to the repeal of the reporting exception for gathering pipelines other than regulated gathering lines as determined in § 192.8. PHMSA plans to adjust the burden for this information collection to account for this addition to the reporting community.

Affected Public: Operators of natural gas and hazardous liquid pipeline systems and operators of liquefied natural gas facilities.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 744.

Estimated annual burden hours: 744.

Frequency of collection: On occasion.

2. *Title:* Qualification of Pipeline Safety Training.

OMB Control Number: 2137–0600.

Current Expiration Date: 04/30/2025.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: 49 CFR part 192 subpart N and part 195 subpart G require all individuals who operate and maintain pipeline facilities to be qualified and keep records of qualification. The purpose of this mandatory information collection request is to ensure compliance with the record keeping requirements prescribed in the federal pipeline safety regulations. Pipeline operators must make and maintain the records as described and have those records available for compliance inspection by PHMSA staff upon request. Examples of such records include the identification of qualified individuals; identification of covered tasks; dates of current qualification; and qualification methods. Records supporting an individual's current qualification shall be maintained while the individual is performing the covered task. Records of prior qualification and records of individuals no longer performing covered tasks shall be retained for a period of five years.

Affected Public: Operators of PHMSA-regulated pipelines.

Annual Reporting and Recordkeeping Burden:

Total Annual Responses: 29,172.

Total Annual Burden Hours: 7,293.

Frequency of Collection: On occasion.

3. *Title:* Hazardous Liquid Integrity Management.

OMB Control Number: 2137–0605.

Current Expiration Date: 04/30/2025.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: Operators of Hazardous Liquid Pipelines are required to document the continual assessment and evaluation of their pipelines' integrity through inspection or testing, as well as remedial preventive, and mitigative actions. In cases where a determination about pipeline threats has not been obtained within 180 days following the date of inspection, pipeline operators must notify PHMSA in writing and provide an expected date when adequate information will become available. Operators must also notify PHMSA if they are unable to assess their pipeline via an in-line inspection. Operators who choose to use an alternate assessment method must demonstrate that their pipeline is not capable of accommodating an in-line inspection tool and that the use of an alternative assessment method will provide a substantially equivalent understanding of the condition of the pipeline. This mandatory record keeping requirement supports the U.S. Department of Transportation's "SAFETY STRATEGIC GOAL" which targets three main strategic initiatives:

managing risk and integrity, sharing responsibility, and providing effective stewardship. This goal enhances public health and safety by working toward the elimination of transportation-related deaths and injuries. This information is used by PHMSA to determine compliance with federal pipeline safety regulations and is also used by Agency and State Officials to assist federal and state pipeline safety inspectors who audit this information when they conduct compliance inspections and to provide background for failure investigations.

Affected Public: Operators of hazardous liquid pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 10,515.

Estimated annual burden hours: 344,807.

Frequency of Collection: On occasion.

4. *Title:* Public Awareness Program.

OMB Control Number: 2137–0622.

Current Expiration Date: 04/30/2025.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: This information collection request would require pipeline operators to develop and implement public awareness programs. The public awareness programs should establish communications and provide information necessary to enhance public understanding of how pipelines function and the public's role in promoting pipeline safety. This mandatory information collection requires operators to submit their completed programs to PHMSA or, in the case of an intrastate pipeline facility operator, the appropriate State agency. The operator's program documentation and evaluation results must also be available for periodic review by appropriate regulatory agencies. This information will be used by PHMSA to evaluate compliance with pipeline safety regulations. The purpose of the collection is to prevent the risks caused by unintentional pipeline releases and their impact on the public and the environment.

Affected Public: Operators of natural gas and hazardous liquid pipelines.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 45,004.

Estimated annual burden hours: 517,546.

Frequency of Collection: On occasion.

5. *Title:* Gas and Liquid Pipeline Safety Program Certification.

OMB Control Number: 2137–0584.

Current Expiration Date: 05/31/2025.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: Section 60105 of 49 U.S.C. sets forth specific requirements a state must meet to qualify for certification status to assume regulatory and enforcement responsibility for intrastate pipelines, *i.e.*, state adoption of minimum federal safety standards, state inspection of pipeline operators to determine compliance with the standards, and state provision for enforcement sanctions substantially the same as those authorized by chapter 601, 49 U.S.C. A state must submit an annual certification to assume responsibility for regulating intrastate pipelines, and states who receive Federal grant funding must have adequate damage prevention plans and associated records in place. PHMSA uses this information to evaluate a state's eligibility for Federal grants and to enforce regulatory compliance. This information collection request requires a participating state to annually submit a Gas Pipeline Safety Program Certification and/or a Hazardous Liquid Pipeline Safety Program Certification to PHMSA's Office of Pipeline Safety (OPS) signifying compliance with the terms of the certification and to maintain records detailing a damage prevention plan for PHMSA inspectors whenever requested. The purpose of the collection is to exercise oversight of the grant program and to ensure that states are compliant with federal pipeline safety regulations.

Affected Public: Operators of pipeline facilities.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 117.
Estimated annual burden hours:

4,473.

Frequency of collection: On occasion.

6. *Title:* Response Plans for Onshore Oil Pipelines.

OMB Control Number: 2137-0589.

Current Expiration Date: 09/30/2025.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: Title 49 CFR part 194 requires an operator of an onshore oil pipeline facility to prepare and submit an oil spill response plan to PHMSA for review and approval. This mandatory recordkeeping requirement details operators' plans to prepare for emergency situations involving oil spills. This mandatory information collection is used by PHMSA to determine if an operator is compliant with the requirements in part 194. Plans are submitted and/or updated annually. This information collection covers

operators' submission of facility response plans for onshore hazardous liquid pipeline facilities.

Affected Public: Operators of onshore oil pipeline facilities.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 540.

Estimated Annual Burden Hours: 73,980.

Frequency of Collection: On occasion.

7. *Title:* Gas Transmission Integrity Management in High Consequence Areas.

OMB Control Number: 2137-0610.

Current Expiration Date: 09/30/2025.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: This mandatory information collection request pertains to gas transmission operators jurisdictional to 49 CFR part 192 subpart O Gas Transmission Integrity Management Program. The information collection requires gas transmission operators in high consequence areas to maintain a written integrity management program and keep records that demonstrate compliance with 49 CFR part 192 subpart O. Operators must maintain their integrity management records for the life of the pipeline, and PHMSA or State regulators may review it as a part of inspections. Gas transmission operators are also required to report to PHMSA certain actions related to their integrity management program. This information collection supports the DOT strategic goal of safety by reducing the number of incidents in natural gas transmission pipelines.

Affected Public: Operators of gas transmission pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated Number of Responses: 733.

Estimated Annual Burden Hours: 1,018,807.

Frequency of Collection: On occasion.

8. *Title:* Control Room Management/ Human Factors.

OMB Control Number: 2137-0624.

Current Expiration Date: 09/30/2025.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: Operators of gas and hazardous liquid pipelines must develop, implement, and submit a human factors management plans designed to reduce risk associated with human factors in each control room. This mandatory record keeping requirement supports the U.S. Department of Transportation's "SAFETY STRATEGIC GOAL" which targets three main strategic initiatives: managing risk and integrity, sharing

responsibility, and providing effective stewardship. This goal enhances public health and safety by working toward the elimination of transportation-related deaths and injuries. The information is used by PHMSA to determine compliance with federal pipeline safety regulations and is also used by Agency and State Officials to assist federal and state pipeline safety inspectors who audit this information when they conduct compliance inspections and to provide background for failure investigations.

Affected Public: Operators of natural gas and hazardous liquid pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated Number of Responses:

11,656.

Estimated Annual Burden Hours: 127,328.

Frequency of Collection: On occasion.

Comments are invited on:

(a) The need for the renewal and revision of these collections of information for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) The accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued in Washington, DC, on October 3, 2024, under authority delegated in 49 CFR 1.97.

John A. Gale,

Director, Standards and Rulemaking Division.

[FR Doc. 2024-23435 Filed 10-9-24; 8:45 am]

BILLING CODE 4910-60-P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Modification to Special Permits

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

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before October 25, 2024.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in

triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH-13, 1200 New Jersey Avenue Southeast, Washington, DC 20590-0001, (202) 366-4535.

SUPPLEMENTARY INFORMATION: Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail

freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

Copies of the applications are available for inspection in the Records Center, East Building, PHH-13, 1200 New Jersey Avenue Southeast, Washington, DC or at <http://regulations.gov>.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on October 1, 2024.

Donald P. Burger,
Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
12303-M	Halliburton Energy Services, Inc.	173.201, 173.301(f), 173.302a, 173.304a.	To modify the special permit to update the minimum wall thickness for the 0.12- and 0.29-gallons sampling cylinders. (modes 1, 2, 3, 4)
14493-M	Aavid Thermacore, Inc	172.101(j), 173.301(f), 173.302a(a)(1), 173.304a(a)(2), 173.306(e).	To modify the special permit to authorize additional hazardous materials in non-DOT specification containers (heat pipes) in the special permit. (modes 1, 2, 3, 4)

[FR Doc. 2024-23410 Filed 10-9-24; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated

Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: This action was issued on October 7, 2024. See **SUPPLEMENTARY INFORMATION** section for relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, 202-622-2420; Assistant Director for Licensing, 202-622-2480; or Assistant Director for Sanctions

Compliance, 202-622-2490 or <https://ofac.treasury.gov/contact-ofac>.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website: <https://ofac.treasury.gov>.

Notice of OFAC Actions

On October 7, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4810-AL-P

Individuals

1. AL-ZEER, Majed (a.k.a. ALZEER, Majed; a.k.a. AL-ZEER, Majed Khalil Moussa; a.k.a. AL-ZEER, Majid), Germany; DOB 12 Aug 1962; alt. DOB 1961 to 1962; POB Bethlehem, West Bank, Palestinian Territories; nationality United Kingdom; alt. nationality Jordan; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Passport 133670754 (United Kingdom) issued 09 Nov 2022; alt. Passport Q721863 (Jordan) issued 28 Sep 2021 (individual) [SDGT] (Linked To: HAMAS).

Designated pursuant to section 1(a)(iii)(A) of Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism," 66 FR 49079, as amended by Executive Order 13886 of September 9, 2019, "Modernizing Sanctions To Combat Terrorism," 84 FR 48041 (E.O. 13224, as amended), for having acted or purported to act for or on behalf of, directly or indirectly, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

2. AL AHMAR, Hamid Abdullah Hussein (Arabic: حميد بن عبد الله الأحمر) (a.k.a. AHMAR, Hamid Abdullah; a.k.a. AHMAR, Hamid Abdullah Hussain; a.k.a. AL AHMAR, Hamid A. H.; a.k.a. AL-AHMAR, Hamid), Istanbul, Turkey; DOB 27 Dec 1967; alt. DOB 01 Jan 1967; POB Sanaa, Yemen; nationality Yemen; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Passport 00030140 (Yemen) expires 09 Apr 2022; Identification Number 99727522148 (Turkey) (individual) [SDGT] (Linked To: HAMAS; Linked To: AL-QUDS INTERNATIONAL FOUNDATION).

Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted, or purported to act for or on behalf of, directly or indirectly, AL-QUDS INTERNATIONAL FOUNDATION, a person whose property and interests in property are blocked pursuant to E.O. 13224.

3. HANOUN, Muhammad Mahoud Ahmad Awad (a.k.a. HANNOUN, Mahid Ahmad Mohammad; a.k.a. HANNOUN, Mohamad Mahmoud Ahmad; a.k.a. HANNOUN, Mohammad Mah'd Ahmed), Via Bartolomeo Parodi N. 79 int.

1a, 16014 Ceranesi, Genoa, Italy; DOB 15 Jun 1962; POB Bodros, Jordan; nationality Jordan; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Passport T1005028 (Italy) expires 21 Jul 2027; National ID No. AX1539488 (Italy); Italian Fiscal Code HNNMMM62H15Z220R (Italy); Residency Number I19693469 (Italy) issued 07 Nov 2023 expires 16 Jun 2033 (individual) [SDGT] (Linked To: IIMAS).

Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

4. DOUGHMAN, Adel Saad al-Din Hassan, Austria; DOB 1963; nationality Austria; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT] (Linked To: HAMAS).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

Entities

1. INVESTRADE PORTFOY YONETIMI ANONIM SİRKETİ (Latin: INVESTRADE PORTFÖY YÖNETİMİ ANONİM ŞİRKETİ) (a.k.a. INVESTRADE PORTFOY YONETIMI A.S. (Latin: INVESTRADE PORTFÖY YÖNETİMİ A.Ş.)), A Girişi, Imrahor Cadessi No. 23 A/1 Gursel Mahallesi 34400 Kagithane, Istanbul, Turkey; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 10 Nov 2017; Tax ID No. 4650572633 (Turkey); Trade License No. 107406 (Turkey) [SDGT] (Linked To: AL AHMAR, Hamid Abdullah Hussein).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, HAMID ABDULLAH HUSSEIN AL AHMAR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

2. AL-INTAJ BANK (a.k.a. PALESTINIAN PRODUCTION BANK), Gaza City, Gaza; Khan Younis, Gaza; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 19 May 2013 to 31 May 2013; Target Type Financial Institution [SDGT] (Linked To: HAMAS).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

3. AL AHMAR OILS SUPPLY AND DISTRIBUTION

(Arabic: الأحمر لتأمين والتوزيع الزيوت), Sanaa, Yemen; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Commercial Registry Number 2008050146 (Yemen) [SDGT] (Linked To: AL AHMAR, Hamid Abdullah Hussein).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, HAMID ABDULLAH HUSSEIN AL AHMAR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

4. AL AHMAR TRADING GROUP (Arabic: مجموعة الأحمر التجارية) (a.k.a. AHMAR GROUP FOR TRADING; a.k.a. AL-AHMAR GROUP FOR TRADE), Sanaa, Yemen; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Commercial Registry Number 960363 (Yemen) [SDGT] (Linked To: AL AHMAR, Hamid Abdullah Hussein).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, HAMID ABDULLAH HUSSEIN AL AHMAR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

5. AL SALAM TRADING AND AGENCIES GENERAL ESTABLISHMENT (Arabic: مؤسسة السلام للتجارة والتوكيلات العامة), Sanaa, Yemen; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Commercial Registry Number 8718 (Yemen) [SDGT] (Linked To: AL AHMAR, Hamid Abdullah Hussein).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, HAMID ABDULLAH HUSSEIN AL AHMAR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

6. SABA, TRADE & INVESTMENT S.R.O. (a.k.a. SABA, TRADE AND INVESTMENT S.R.O.), Prague, Czech Republic; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 22 Oct 2014; Organization Type: Real estate activities with own or leased property; Identification Number 035 09 184 (Czech Republic); Trade License No. 3509184 (Czech Republic); File Number C 232697/MSPH (Czech Republic) [SDGT] (Linked To: AL AHMAR, Hamid Abdullah Hussein).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, HAMID ABDULLAH HUSSEIN AL AHMAR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

7. SABAFON INTERNATIONAL SAL OFFSHORE

(Arabic: سابفون انترناشونال ليمنيد ش.م.ل اوف شور), Sami Al Solh Street, Makram

Building, 6th Floor, Property No. 4110/ Chiyah Section No. 20, Beirut, Lebanon; Beirut, Lebanon; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 15 May 2013; Organization Type: Other business support service activities n.e.c.; Registration Number 1806771 (Lebanon) [SDGT] (Linked To: AL AHMAR, Hamid Abdullah Hussein).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, HAMID ABDULLAH HUSSEIN AL AHMAR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

8. SABATURK DIS TICARET ANONIM SİRKETİ (Latin: SABATURK DIŞ TİCARET ANONİM ŞİRKETİ) (a.k.a. SABATURK FOREIGN TRADE JOINT STOCK COMPANY; a.k.a. SABATURK GAYRİMENKUL GELİSTİRME ANONİM SİRKETİ; a.k.a. SABATURK REAL ESTATE DEVELOPMENT JOINT STOCK COMPANY), Bağcılar, Mahmut Bey District, Istanbul, Turkey; Altunizade Mah. Kisikli Cad. Haluk Turksoy Arkasi Sok. N:2/1 Uskudar, Istanbul, Turkey; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 21 Dec 2015; Organization Type: Real estate activities with own or leased property; Tax ID No. 7360642469 (Turkey); Chamber of Commerce Number 14375-5 (Turkey); Registration Number 0736-0642-4690-0018 (Turkey) [SDGT] (Linked To: AL AHMAR, Hamid Abdullah Hussein).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, HAMID ABDULLAH HUSSEIN AL AHMAR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

9. SAMA INTERNATIONAL MEDIA (Arabic: سماء للإعلام الدولي), Sanaa, Yemen; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Type: Other business support service activities n.e.c.; Business Registration Number 239978 (Yemen) [SDGT] (Linked To: AL AHMAR, Hamid Abdullah Hussein).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, HAMID ABDULLAH HUSSEIN AL AHMAR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

10. VIVID ENERJİ YATIRIMLARI ANONİM SİRKETİ (Latin: VIVID ENERJİ YATIRIMLARI ANONİM ŞİRKETİ), Gursel Mah. Imrahor CAD. No:23 A/1 Kagithane, Istanbul, Turkey; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 21 Mar 2019; Organization Type: Other business support service activities n.e.c.; Identification Number 0925084467700001 (Turkey); Chamber of Commerce Number 185388-5 (Turkey) [SDGT] (Linked To: AL AHMAR, Hamid Abdullah Hussein).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, HAMID ABDULLAH HUSSEIN AL AHMAR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

11. ASSOCIAZIONE BENEFICA DI SOLIDARIETA CON IL POPOLO PALESTINESE (Latin: ASSOCIAZIONE BENEFICA DI SOLIDARIETA CON IL POPOLO PALESTINESE) (a.k.a. CHARITY ASSOCIATION OF SOLIDARITY WITH THE PALESTINIAN PEOPLE; a.k.a. "ABSPP"), Genova, Italy; Rome, Italy; Milan, Italy; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 01 Jan 1994 to 31 Dec 1994; Target Type Charity or Nonprofit Organization [SDGT] (Linked To: HAMAS).

Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

Lisa M. Palluconi,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2024-23445 Filed 10-9-24; 8:45 am]

BILLING CODE 4810-AL-C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request on Burden Related to the Failure of Employers To Make Comparable Health Savings Account Contributions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the burden related to the failure of employers to make comparable health savings account contributions.

DATES: Written comments should be received on or before December 9, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andrés Garcia, Internal Revenue

Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov. Please include, "OMB Number: 1545-2146—Public Comment Request Notice" in the Subject line.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the form and instructions should be directed to Ronald J. Durbala, at (202) 317-5746, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at RJoseph.Durbala@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Failure of Employer to Make Comparable Health Savings Account Contributions.

OMB Number: 1545-2146.

Document Number: Form 8928.

Abstract: Under section 4980G, an excise tax is imposed on an employer that fails to make comparable contributions to the HSAs of its employees. Form 8928 is used to report payment of excise taxes by employers and group plans under Code sections 4980B, 4980D, 4980F and 4980G.

Current Actions: There are no changes to the burden previously approved.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit organizations, and individuals.

Estimated Number of Respondents: 68.

Estimated Time per Respondent: 23 hrs., 29 min.

Estimated Total Annual Burden Hours: 1,597.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected; and

- Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology, *e.g.*, by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: October 7, 2024.

Ronald J. Durbala,
IRS Tax Analyst.

[FR Doc. 2024–23433 Filed 10–9–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Art Advisory Panel—Notice of Availability of Report of 2023 Closed Meetings

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice.

SUMMARY: A report summarizing the closed meeting activities of the Art Advisory Panel during fiscal year 2023 has been prepared. A copy of this report has been filed with the Assistant Secretary for Management of the Department of the Treasury.

DATES: *Applicable Date:* This notice is applicable September 12, 2024.

ADDRESSES: The report is available at <https://www.irs.gov/compliance/appeals/art-appraisal-services>.

FOR FURTHER INFORMATION CONTACT: Krista M. Floyd, AP:SPR:AREA 10:AAS, Internal Revenue Service/Independent Office of Appeals, 2203 N Lois Avenue, Tampa, FL 33607–2370, Telephone number (813) 367–8444 (not a toll free number).

SUPPLEMENTARY INFORMATION: It has been determined that this document is not a major rule as defined in Executive Order 12291 and that a regulatory impact analysis is, therefore, not required. Additionally, this document does not constitute a rule subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6).

Authority: 5 U.S.C. 1009(d), of the Federal Advisory Committee Act, and 5 U.S.C. 552b, of the Government in the Sunshine Act.

Elizabeth P. Askey,
Acting Chief, Independent Office of Appeals.

[FR Doc. 2024–23431 Filed 10–9–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request on Burden Related to Completing Form SS–4 and SS–4 (SP)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the burden for completing the form SS–4, *Application for Employer Identification Number*, and Form SS–4 (SP), *Solicitud de Número de Identificación del Empleador (EIN)*.

DATES: Written comments should be received on or before December 9, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andrés Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov. Please include, “OMB Number: 1545–0003—Public Comment Request Notice” in the Subject line.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Ronald J. Durbala, at (202) 317–5746, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at RJoseph.Durbala@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Application for Employer Identification Number.

OMB Number: 1545–0003.

Document Number: Forms SS– and SS–4 (SP).

Abstract: Taxpayers who are required to have an identification number for use on any return, statement, or other document must prepare and file Form SS–4 or Form SS–4 (SP) to obtain a number. The information is used by the Internal Revenue Service and the Social Security Administration in tax administration and by the Bureau of the Census for business statistics.

Current Actions: There are no changes being made to the forms at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, not-for-profit institutions, farms, Federal Government, and State, local or Tribal governments.

Estimated Number of Respondents: 5,965,735.

Estimated Time per Respondent: 33 min.

Estimated Total Annual Burden Hours: 3,340,812.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected; and

- Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: October 7, 2024.

Ronald J. Durbala,
IRS Tax Analyst.

[FR Doc. 2024–23462 Filed 10–9–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY**Internal Revenue Service****Proposed Collection; Comment Request on Declarations and Authorizations for Electronic Filing**

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning, Declarations and Authorizations for Electronic Filing.

DATES: Written comments should be received on or before December 9, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov. Include "OMB Number 1545-0967—Declarations and Authorizations for Electronic Filing" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of this collection should be directed to Martha R. Brinson, at (202) 317-5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at Martha.R.Brinson@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Declarations and Authorizations for Electronic Filing.

OMB Number: 1545-0967.

Form Number: 8453-EG, 8453-WH, 8879-EG, and 8879-WH.

Abstract: The IRS is actively engaged in encouraging e-filing and electronic documentation. The Form 8453 series is used to authenticate the electronically filed tax return, authorize the electronic return originator (ERO) or intermediate service provider (ISP) to transmit the return, and provide the taxpayer's consent to authorize electronic funds withdrawal for payment of taxes owed. The Form 8879 series is used authorize the taxpayer and ERO to sign the return using a personal identification number (PIN) and consent to an electronic funds withdrawal.

Current Actions: There is a change to the existing collection. Forms 8453-EG and 8879-EG are new forms developed

for United States Gift (and Generation-Skipping Transfer) Tax Return.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households, and Business or other for-profit organizations.

Estimated Number of Responses: 226,400.

Estimated Time per Respondent: 1.99 hours.

Estimated Total Annual Burden Hours: 450,520.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 7, 2024.

Martha R. Brinson,
Tax Analyst.

[FR Doc. 2024-23439 Filed 10-9-24; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0045]

Agency Information Collection Activity: VA Request for Determination of Reasonable Value

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Comments must be received on or before December 9, 2024.

ADDRESSES: Comments must be submitted through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Program-Specific information: Nancy J. Kessinger, 202-632-8924, Nancy.Kessinger@va.gov.

VA PRA information: Maribel Aponte, 202-461-8900, vacopaperworkreduact@va.gov.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: VA Request for Determination of Reasonable Value (VA Forms 26-1805, and 26-1805-1).

OMB Control Number: 2900-0045. <https://www.reginfo.gov/public/do/PRASearch> (Once at this link, you can enter the OMB Control Number to find the historical versions of this Information Collection).

Type of Review: Revision of a currently approved collection.

Abstract: VA utilizes Form 26-1805 (paper form) and 26-1805-1 (digital form) for lenders to request an appraisal and assign an appraiser (*i.e.*, "ordering" an appraisal), which ultimately provides the appraiser with the authority to be on

the property to conduct the appraisal (*i.e.*, an engagement letter). This information collection request seeks to expand this data collection clearance to encompass a modernized, end-to-end appraisal management process. Under this ICR extension, VA will capture information from lenders around when an appraisal has been ordered (current VA Form 26–1805), but will also capture information and workflow

associated with the assignment, scheduling, and review of an appraisal by VA or a lender. This process will be consistent with the rest of the mortgage industry, and will align VA's appraisal process with the industry standard.

Affected Public: Individuals and households.

Estimated Annual Burden: 467,100 hours.

Estimated Average Burden per Respondent: 9 minutes.

Frequency of Response: One-time per appraisal.

Estimated Number of Respondents: 519,000.

Authority: 44 U.S.C. 3501 *et seq.*

Dorothy Glasgow,

VA PRA Clearance Officer (Alt.), Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–23409 Filed 10–9–24; 8:45 am]

BILLING CODE 8320–01–P



FEDERAL REGISTER

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Part II

Department of Health & Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 600

45 CFR Parts 153, 155, 156, et al.

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2026; and Basic Health Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 600

Office of the Secretary

45 CFR Parts 153, 155, 156, and 158

[CMS–9888–P]

RIN 0938–AV41

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2026; and Basic Health Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule includes payment parameters and provisions related to the HHS-operated risk adjustment and risk adjustment data validation (HHS–RADV) programs, as well as 2026 benefit year user fee rates for issuers that participate in the HHS-operated risk adjustment program and the 2026 benefit year user fee rates for issuers offering qualified health plans (QHPs) through Federally-facilitated Exchanges (FFE)s and State-based Exchanges on the Federal platform (SBE–FPs). This proposed rule also includes proposed requirements related to modifications to the calculation of the Basic Health Program (BHP) payment; and changes to the Initial Validation Audit (IVA) sampling approach and Second Validation Audit (SVA) pairwise means test for HHS–RADV. It also addresses HHS' authority to engage in compliance reviews of and take enforcement action against lead agents of insurance agencies for violations of HHS' Exchange standards and requirements; HHS' system suspension authority to address noncompliance by agents and brokers; an optional fixed-dollar premium payment threshold; proposed reconsideration standards for certification denials; proposed changes to the approach for conducting Essential Community Provider (ECP) certification reviews; a proposal to publicly share aggregated, summary-level Quality Improvement Strategy (QIS) information on an annual basis; and proposed revisions to the medical loss ratio (MLR) reporting and rebate requirements for qualifying issuers that meet certain standards.

DATES: To be assured consideration, comments must be received at one of

the addresses provided below, by November 12, 2024.

ADDRESSES: In commenting, please refer to file code CMS–9888–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.
2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9888–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9888–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Jeff Wu, (301) 492–4305, Rogelyn McLean, (301) 492–4229, Grace Bristol, (410) 786–8437, for general information.

Ayesha Anwar, (301) 492–4000, Joshua Paul, (301) 492–4347, or Debbie Noymer, (301) 448–3755 for matters related to HHS-operated risk adjustment.

Leanne Scott, (410) 786–1045 or Ayesha Anwar, (301) 492–4000 for matters related to HHS-operated risk adjustment data validation.

Aaron Franz, (410) 786–8027, for matters related to user fees.

Brian Gubin, (410) 786–1659, for matters related to agent, broker, and web-broker guidelines.

Zarin Ahmed, (301) 492–4400, for matters related to enrollment of qualified individuals into QHPs and termination of Exchange enrollment or coverage for qualified individuals.

Christina Whitefield, (301) 492–4172, for matters related to the medical loss ratio program.

Preeti Hans, (301) 492–5144, for matters related to Quality Improvement Strategy.

Ken Buerger, (410) 786–1190, for matters related to certification standards for QHPs.

Nikolas Berkobien, (667) 290–9903, for matters related to standardized plan options, non-standardized plan option

limits and exceptions, and financial requirements for issuers of QHPs on the FFEs.

Adelaide Balenger, (667) 414–0691, for matters related to the Actuarial Value Calculator.

Mary Evans, (470) 890–4113, for matters related to the Failure to File and Reconcile process.

Chris Truffer, (410) 786–1264, for matters related to the Basic Health Program (BHP) provision.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a summary of not more than 100 words in length of this proposed rule, in plain language, may be found at <https://www.regulations.gov/>.

Intention of Future Rulemaking: HHS and the Departments of Labor and Treasury intend to issue a future notice of proposed rulemaking address the issues arising out of *HIV and Hepatitis Policy Institute et al. v. U.S. Department of Health and Human Services et al.*, Civil Action No. 22–2604 (D.D.C. Sept. 29, 2023), namely, the applicability of drug manufacturer support to the annual limitation on cost sharing.

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I. Executive Summary

We are proposing changes to the provisions and parameters implemented through prior rulemaking to implement the ACA.¹ These proposed requirements are published under the authority granted to the Secretary by the ACA and the PHS Act.² In this proposed rule, we are proposing changes related to some of

the ACA provisions and parameters we previously implemented and are proposing new provisions. Our goal with these proposed requirements is providing quality, affordable coverage to consumers while minimizing administrative burden and ensuring program integrity. The changes proposed in this rule are also intended to help advance health equity, mitigate health disparities, and alleviate discrimination.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the PHS Act to establish various reforms to the group and individual health insurance markets.

These provisions of the PHS Act were later augmented by other laws, including the ACA.

Subtitles A and C of title I of the ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The term “group health plan” includes both insured and self-insured group health plans.

Section 2718 of the PHS Act, as added by the ACA, generally requires health insurance issuers in the group and individual markets to submit an annual medical loss ratio (MLR) report to HHS and provide rebates to enrollees if the issuers do not achieve specified MLR thresholds.

Section 1301(a)(1)(B) of the ACA directs all issuers of qualified health plans (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 Actuarial Value (AV) levels established in section 1302(d) of the ACA. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the requirement to cover the EHB package to non-grandfathered individual and small group health insurance coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in section 1302(c)(1) of the ACA.

Section 1302 of the ACA provides for the establishment of an EHB package

that includes coverage of EHBs (as defined by the Secretary of HHS), cost-sharing limits, and AV requirements. The law directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

Sections 1302(b)(4)(A) through (D) of the ACA establish that the Secretary must define EHB in a manner that: (1) reflects appropriate balance among the 10 categories; (2) is not designed in such a way as to discriminate based on age, disability, or expected length of life; (3) takes into account the health care needs of diverse segments of the population; and (4) does not allow denials of EHBs based on age, life expectancy, disability, degree of medical dependency, or quality of life.

Section 1302(d) of the ACA describes the various levels of coverage based on 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.

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(d)(4)(A) of the ACA requires the Exchange to implement procedures for the certification, recertification, and decertification of health plans as QHPs, consistent with guidelines developed by the Secretary under section 1311(c) of the ACA. Section 1311(e)(1) of the ACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary’s requirements for certification issued under section 1311(c) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the State. Section 1311(c)(6)(C) of the ACA directs the Secretary of HHS to

¹ The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this rulemaking, the two statutes are referred to collectively as the “Patient Protection and Affordable Care Act,” “Affordable Care Act,” or “ACA.”

² See sections 1301, 1302, 1311, 1312, 1313, 1321, 1331, and 1343 of the ACA and sections 2718 and 2792 of the PHS Act.

require an Exchange to provide for special enrollment periods and section 1311(c)(6)(D) of the ACA directs the Secretary of HHS to require an Exchange to provide for a monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.

Section 1311(d)(3)(B) of the ACA permits a State, at its option, to require QHPs to cover benefits in addition to EHB. This section also requires a State to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional State-required benefits.

Section 1312(c) of the ACA generally requires a health insurance issuer to consider all enrollees in all health plans (except grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual and small group market risk pools under section 1312(c)(3) of the ACA.

Section 1312(e) of the ACA provides the Secretary with the authority to establish procedures under which a State may allow agents or brokers to (1) enroll qualified individuals and qualified employers in QHPs offered through Exchanges and (2) assist individuals in applying for advance payments of the premium tax credit (APTC) and cost-sharing reductions (CSRs) for QHPs sold through an Exchange.

Section 1312(f)(1)(B) of the ACA provides that an individual shall not be treated as a qualified individual for enrollment in a QHP if, at the time of enrollment, the individual is incarcerated, other than incarceration pending the disposition of charges.

Sections 1313 and 1321 of the ACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1313(a)(5)(A) of the ACA provides the Secretary with the authority to implement any measure or procedure that the Secretary determines is appropriate to reduce fraud and abuse in the administration of the Exchanges. Section 1321 of the ACA provides for State flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of the ACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other

components of title I of the ACA, including such other requirements as the Secretary determines appropriate. When operating an FFE under section 1321(c)(1) of the ACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the ACA to collect and spend user fees. Office of Management and Budget (OMB) Circular A–25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the 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 1331 of the ACA provides States with an option to establish a Basic Health Program (BHP). In the States that elect to operate a BHP, the BHP makes affordable health benefits coverage available for individuals under age 65 with household incomes between 133 percent and 200 percent of the Federal poverty level (FPL) who are not otherwise eligible for Medicaid, the Children's Health Insurance Program (CHIP), or affordable employer-sponsored coverage, or for individuals whose income is equal to or below 200 percent of FPL but are lawfully present non-citizens ineligible for Medicaid. For those States that have expanded Medicaid coverage under section 1902(a)(10)(A)(i)(VIII) of the Social Security Act (the Act), the lower income threshold for BHP eligibility is effectively 138 percent of the FPL due to the application of a required 5 percent income disregard in determining the upper limits of Medicaid income eligibility (section 1902(e)(14)(I) of the Act).

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 charges collected from those issuers that attract lower-than-average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees. Section 1343(b) of the ACA provides that the Secretary, in consultation with States, shall establish criteria and methods to be used in carrying out the risk adjustment activities under this section. Consistent with section 1321(c) of the ACA, the Secretary is responsible for

operating the HHS risk adjustment program in any State that fails to do so.³

Section 1401(a) of the ACA added section 36B to the Internal Revenue Code (the Code), which, among other things, requires that a taxpayer reconcile APTC for a year of coverage with the amount of the premium tax credit (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(f) of the ACA requires the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Homeland Security, and the Commissioner of Social Security, to establish procedures for hearing and making decisions governing appeals of Exchange eligibility determinations. Section 1411(f)(1)(B) of the 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 purpose of, and to the extent necessary for, ensuring 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 1413 of the ACA directs the Secretary to establish, subject to minimum requirements, a streamlined enrollment process for enrollment in QHPs and all insurance affordability programs.

Section 5000A of the Code, as added by section 1501(b) of the ACA, requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act, which was enacted on December 22, 2017, the individual shared responsibility payment is reduced to \$0, effective for months beginning after December 31, 2018. Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals aged 30 and above qualify to enroll in

³ In the 2014 through 2016 benefit years, HHS operated the risk adjustment program in every State and the District of Columbia, except Massachusetts. Beginning with the 2017 benefit year, HHS has operated the risk adjustment program in all 50 States and the District of Columbia.

catastrophic coverage under §§ 155.305(h) and 156.155(a)(5).

Section 1902(r)(2)(A) of the Act permits States to apply less restrictive methodologies than cash assistance program methodologies in determining eligibility for certain eligibility groups.

1. Premium Stabilization Programs

The premium stabilization programs refer to the risk adjustment, risk corridors, and reinsurance programs established by the ACA.⁴ For past rulemaking, we refer readers to the following rules:

- In the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule), we implemented the premium stabilization programs.

- In the March 11, 2013 **Federal Register** (78 FR 15409) (2014 Payment Notice), we finalized the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs.

- In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the modification to the HHS risk adjustment methodology related to community rating States.

- In the November 6, 2013 **Federal Register** (78 FR 66653), we issued a correcting amendment to the 2014 Payment Notice to address how an enrollee's age for the risk score calculation would be determined under the HHS 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 establish payment parameters in those programs.

- In the May 27, 2014 **Federal Register** (79 FR 30240), we announced the fiscal year 2015 sequestration rate for the HHS-operated 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 establish 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 establish the payment parameters in those programs.

- In the December 22, 2016 **Federal Register** (81 FR 94058) (2018 Payment Notice), we finalized the benefit and payment parameters for the 2018 benefit year, added the high-cost risk pool parameters to the HHS risk adjustment methodology, incorporated prescription drug factors in the adult models, established enrollment duration factors for the adult models, and finalized policies related to the collection and use of enrollee-level External Data Gathering Environment (EDGE) data.

- In the April 17, 2018 **Federal Register** (83 FR 16930) (2019 Payment Notice), we finalized the benefit and payment parameters for the 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 error rate methodology for HHS–RADV adjustments to transfers.

- In the May 11, 2018 **Federal Register** (83 FR 21925), we issued a correction to the 2019 HHS risk adjustment coefficients in the 2019 Payment Notice.

- On July 27, 2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final HHS risk adjustment model coefficients to reflect an additional recalibration related to an update to the 2016 enrollee-level EDGE data set.⁵

- In the July 30, 2018 **Federal Register** (83 FR 36456), we adopted the 2017 benefit year HHS risk adjustment methodology as established in the final rules issued in the March 23, 2012 (77 FR 17220 through 17252) and March 8, 2016 (81 FR 12204 through 12352) editions of the **Federal Register**. The final rule set forth an additional explanation of the rationale supporting the use of Statewide average premium in the State payment transfer formula for the 2017 benefit year, including the reasons why the program is operated by HHS in a budget-neutral manner. The final rule also permitted HHS to resume 2017 benefit year HHS risk adjustment payments and charges. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of the publication of the final rule.

- In the December 10, 2018 **Federal Register** (83 FR 63419), we adopted the 2018 benefit year HHS risk adjustment methodology as established in the final rules issued 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 State payment transfer formula for the 2018 benefit year, including the reasons why the program is operated by HHS 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 the 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 HHS 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 issued the 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients on the CCIIO website.⁶

- In the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice), we finalized the benefit and payment parameters for the 2021 benefit year, as well as adopted updates to the HHS risk adjustment models' hierarchical condition categories (HCCs) to transition to the 10th revision of the International Statistical Classification of Diseases (ICD–10) codes, approved the request from Alabama to reduce HHS risk adjustment transfers by 50 percent in the 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

⁴ See section 1341 of the ACA (transitional reinsurance program), section 1342 of the ACA (risk corridors program), and section 1343 of the ACA (risk adjustment program).

⁵ CMS. (2018). *Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients*. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf>.

⁶ CMS. (2020). *Final 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients*. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf>.

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 HHS 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) (part 2 of the 2022 Payment Notice), we finalized a subset of proposals from the December 4, 2020 **Federal Register** (85 FR 78572) (the 2022 Payment Notice proposed rule), including policy and regulatory revisions related to the HHS-operated risk adjustment program, finalization of the benefit and payment parameters for the 2022 benefit year, and approval of the request from Alabama to reduce HHS 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 HHS risk adjustment adult model coefficients.⁷

- In the May 6, 2022 **Federal Register** (87 FR 27208) (2023 Payment Notice), we finalized revisions related to the HHS-operated risk adjustment program, including the benefit and payment parameters for the 2023 benefit year, HHS risk adjustment model recalibration, and policies related to the collection and extraction of enrollee-level EDGE data. We also finalized the adoption of the interacted HCC count specification for the adult and child models, along with modified enrollment duration factors for the adult models, beginning with the 2023 benefit year.⁸

We also repealed the ability for States, other than prior participants, to request a reduction in HHS risk adjustment State transfers starting with the 2024 benefit year. In addition, we approved a 25 percent reduction to 2023 benefit year HHS risk adjustment transfers in Alabama’s individual market and a 10 percent reduction to 2023 benefit year HHS risk adjustment transfers in Alabama’s small group market. We also finalized further refinements to the HHS–RADV error rate calculation methodology beginning with the 2021 benefit year.

- In the April 27, 2023 **Federal Register** (88 FR 25740) (2024 Payment Notice), we finalized the benefit and payment parameters for the 2024 benefit year, amended the EDGE discrepancy materiality threshold and data collection requirements, and reduced the risk adjustment user fee. For the 2024 benefit year, we approved 50 percent reductions to HHS risk adjustment transfers for Alabama’s individual and small group markets, and repealed prior participant States’ ability to request reductions of their risk adjustment transfers for the 2025 benefit year and beyond. We finalized several refinements to HHS–RADV program requirements, such as shortening the window to confirm SVA findings or file a discrepancy report, changing the HHS–RADV materiality threshold for random and targeted sampling, and no longer exempting exiting issuers from adjustments to risk scores and HHS risk adjustment transfers when they are negative error rate outliers. We also announced the discontinuance of the Lifelong Permanent Condition List (LLPC) and Non-EDGE Claims (NEC) in HHS–RADV beginning with the 2022 benefit year.

- In the April 15, 2024 **Federal Register** (89 FR 26218) (2025 Payment Notice), we finalized the benefit and payment parameters for the 2025 benefit year, including the 2025 risk adjustment models and updated the adjustment factors for the receipt of CSRs for the American Indian and Alaska Native (AI/AN) subpopulation who are enrolled in zero and limited cost-sharing plans to improve prediction in the HHS risk adjustment models. In addition, we finalized that in certain cases, we may require a corrective action plan (CAP) to address an observation identified in an HHS risk adjustment program audit.

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” issued in the August 30, 2013 **Federal Register** (78 FR 54069), and the “second Program Integrity Rule” issued 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 final rule (2019 Program Integrity Rule) issued in the December 27, 2019 **Federal Register** (84 FR 71674).

In the April 27, 2023 **Federal Register** (88 FR 25740) (2024 Payment Notice), we finalized a policy to implement improper payment pre-testing and assessment (IPPTA) requirements for State Exchanges to ensure adherence to the Payment Integrity Information Act of 2019. In addition, we finalized allowing additional time for HHS to review evidence submitted by agents and brokers to rebut allegations pertaining to Exchange agreement suspensions or terminations. We also introduced consent and eligibility application documentation requirements for agents, brokers, and web-brokers that assist Exchange consumers in FFE and SBE–FP States.

3. Market Rules

In the February 27, 2013 **Federal Register** (78 FR 13406), we issued the health insurance market rules, including provisions related to the single risk pool. We amended requirements related to index rates under the single risk pool provision in a final rule issued in the July 2, 2013 **Federal Register** (78 FR 39870). In the October 30, 2013 **Federal Register** (78 FR 65046), we clarified when issuers may establish and update premium rates. In the March 8, 2016 **Federal Register** (81 FR 12203), we clarified single risk pool provisions related to student health insurance coverage. We finalized minor adjustments to the single risk pool regulations in the 2018 Payment Notice, issued in the December 22, 2016 **Federal Register** (81 FR 94058).

4. Exchanges

We issued 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 18310) (Exchange Establishment Rule), we implemented the Affordable Insurance Exchanges (Exchanges), consistent with title I of the ACA, to provide competitive marketplaces for individuals and small employers to directly compare available private health insurance options on the basis of price, quality, and other factors. This

⁷ CMS. (2021). 2022 Benefit Year Final HHS Risk Adjustment Model Coefficients. <https://www.cms.gov/files/document/updated-2022-benefit-year-final-hhs-risk-adjustment-model-coefficients-clean-version-508.pdf>.

⁸ CMS (2022). 2023 Benefit Year Final HHS Risk Adjustment Model Coefficients. <https://www.cms.gov/files/document/2023-benefit-year-final-hhs-risk-adjustment-model-coefficients.pdf>.

included implementation of components of the Exchanges and standards for eligibility for Exchanges, as well as network adequacy and essential community provider (ECP) certification standards.

In the August 17, 2011 **Federal Register** (76 FR 51201), we issued a proposed rule regarding eligibility determinations, including the regulatory requirement to verify incarceration status. In the March 27, 2012 **Federal Register** (77 FR 18310) we finalized the regulatory requirement to verify incarceration attestation using an approved electronic data source that is current and accurate, and to resolve the inconsistency when attestations are not reasonably compatible with information in an approved data source. We also established requirements regarding accessible communications for individuals with disabilities and those with LEP.

In the 2014 Payment Notice and the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, issued 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, issued 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 the 2018 Payment Notice, issued in the December 22, 2016 **Federal Register** (81 FR 94058), we set forth the standards for the request for reconsideration of denial of certification specific to the FFEs at § 155.1090.

In an interim final rule, issued 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, issued in the December 22, 2016 **Federal Register** (81 FR 94058).

In the Market Stabilization final rule, issued in the April 18, 2017 **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice, issued 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 2020 Payment Notice established a new special enrollment period.

In the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice), we finalized revisions to the parameters of special enrollment periods and the quality rating information display standards for State Exchanges and amended the periodic data matching requirements.

In the January 19, 2021 **Federal Register** (86 FR 6138) (part 1 of the 2022 Payment Notice), we 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 issued part 2 of the 2022 Payment Notice. In part 3 of the 2022 Payment Notice, issued in the September 27, 2021 **Federal Register** (86 FR 53412), in conjunction with the Department of the Treasury, we finalized amendments to certain policies in part 1 of the 2022 Payment Notice.

In the May 6, 2022 **Federal Register** (87 FR 27208), we finalized changes to maintain the user fee rate for issuers offering plans through the FFEs and maintain the user fee rate for issuers offering plans through the SBE-FPs for the 2023 benefit year. We also finalized various policies to address certain agent, broker, and web-broker practices and conduct. We also finalized updates to the requirement that all Exchanges conduct special enrollment period verifications.

In the 2024 Payment Notice, issued in the April 27, 2023 **Federal Register** (88 FR 25740), we revised Exchange Blueprint approval timelines, lowered the user fee rate for QHPs in the FFEs and SBE-FPs, and amended re-enrollment hierarchies for enrollees. We also finalized policies to update FFE and SBE-FP standardized plan options; reduced the risk of plan choice overload on the FFEs and SBE-FPs by limiting the number of non-standardized plan options that issuers may offer through Exchanges on the Federal platform to four for PY 2024 and to two for PY 2025 and subsequent years; and ensure correct QHP information. In addition, we amended coverage effective date rules, lengthened the special enrollment period from 60 to 90 days for those who lose Medicaid coverage, and prohibited QHPs on FFEs and SBE-FPs from terminating coverage mid-year for dependent children who reach the applicable maximum age. We also finalized policies on verifying consumer income and permitting door-to-door assisters to solicit consumers. To ensure provider network adequacy, we finalized provider network and ECP

policies for QHPs. We revised the failure to file and reconcile process to ensure enrollees would not lose APTC eligibility until they or their tax filer failed to file their Federal income taxes and reconcile APTC for two consecutive tax years.

In the 2025 Payment Notice, issued in the April 15, 2024 **Federal Register** (89 FR 26218), we required a State seeking to operate a State Exchange to first operate an SBE-FP for at least one plan year, revised Exchange Blueprint requirements for States transitioning to a State Exchange, established additional minimum standards for Exchange call center operations, required an Exchange to operate a centralized eligibility and enrollment platform on its website, and finalized various policies for web-brokers and direct enrollment entities. In addition, we required State Exchanges and State Medicaid agencies to remit payment to HHS for their use of certain income data, amended re-enrollment hierarchies for enrollees enrolled in catastrophic coverage, revised the parameters around a State Exchange adopting an alternative open enrollment period, and extended the availability of a special enrollment period for APTC-eligible qualified individuals with a projected annual household income no greater than 150 percent of the Federal Poverty Level (FPL). To ensure provider network adequacy in State Exchanges and SBE-FPs, we finalized provider network adequacy policies applicable to such Exchanges for PY 2026 and subsequent plan years. We also further lowered the user fee rate for QHPs in the FFEs and SBE-FPs. In addition, we finalized the policy to maintain FFE and SBE-FP standardized plan option metal levels from the 2024 Payment Notice and finalized an exceptions process to the limitation on non-standardized plan options in FFEs and SBE-FPs. We also finalized the requirement for Exchanges to provide notification to enrollees or their tax filers who have failed to file their Federal income taxes and reconcile APTC for one tax year.

5. Essential Health Benefits

We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was issued in the February 25, 2013 **Federal Register** (78 FR 12834) (EHB Rule). We established at § 156.135(a) that AV is generally to be calculated using the AV Calculator developed and made available by HHS for a given benefit year. In the 2015 Payment Notice (79 FR 13743), we established at § 156.135(g) provisions

for updating the AV Calculator in future plan years. In the 2017 Payment Notice (81 FR 12349), we amended the provisions at § 156.135(g) to allow for additional flexibility in our approach and options for updating of the AV Calculator.

In the 2025 Payment Notice, issued in the April 15, 2024 **Federal Register** (89 FR 26218), we revised § 155.170(a) to codify that benefits covered in a State's EHB-benchmark plan are not considered in addition to EHB, even if they had been required by State action taking place after December 31, 2011, other than for purposes of compliance with Federal requirements. We finalized three revisions to the standards for State selection of EHB-benchmark plans for benefit years beginning on or after January 1, 2026: we revised the typicality standard at § 156.111 for States to demonstrate that their new EHB-benchmark plan provides a scope of benefits that is equal to that of a typical employer plan in the State and removed the generosity standard; removed the requirement for States to submit a formulary drug list as part of their application unless they are changing their prescription drug EHBs; and consolidated the options for States to change their EHB-benchmark plans. We also removed the regulatory prohibition at § 156.115(d) on issuers from including routine non-pediatric dental services as an EHB beginning with PY 2027. In addition, we revised § 156.122 to codify that prescription drugs in excess of those covered by a State's EHB-benchmark plan are considered EHB. We also stated that HHS and the Departments of Labor and the Treasury intend to propose rulemaking that would align the standards applicable to large group market health plans and self-insured group health plans with those applicable to individual and small group market plans, so that all group health plans and health insurance coverage subject to sections 2711 and 2707(b) of the PHS Act, as applicable, would be required to treat prescription drugs covered by the plan or coverage in excess of the applicable EHB-benchmark plan as EHB for purposes of the prohibition of lifetime and annual limits and the annual limitation on cost sharing, which would further strengthen the consumer protections in the ACA.

6. Medical Loss Ratio (MLR)

We issued a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297) and issued an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75

FR 74864). A final rule with a 30-day comment period was issued in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was issued in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was issued in the **Federal Register** on May 16, 2012 (77 FR 28790). The MLR program requirements were amended in final rules issued 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), the May 5, 2021 **Federal Register** (86 FR 24140), and the May 6, 2022 **Federal Register** (87 FR 27208), and an interim final rule that was issued in the September 2, 2020 **Federal Register** (85 FR 54820).

7. Quality Improvement Strategy

We issued regulations in § 155.200(d) to direct Exchanges to evaluate quality improvement strategies, and § 156.200(b) to 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, issued 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 quality improvement strategy standards for QHPs offered through an Exchange.

8. Basic Health Program

In the March 12, 2014, **Federal Register** (79 FR 14111), we issued a final rule entitled the "Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity" (hereinafter referred to as the BHP final rule) implementing section 1331 of the ACA, which governs the establishment of BHPs. The BHP final rule established the standards for State and Federal administration of BHPs, including provisions regarding eligibility and enrollment, benefits, cost-sharing requirements and oversight activities. In

the BHP final rule, we specified that the BHP Payment Notice process would include the annual publication of both a proposed and final BHP payment methodology.

On October 11, 2017, the Attorney General of the United States provided HHS and the Department of the Treasury (the Departments) with a legal opinion⁹ indicating that the permanent appropriation at 31 U.S.C. 1324, from which the Departments had historically drawn funds to make CSR payments, cannot be used to fund CSR payments to insurers. In light of this opinion—and in the absence of any other appropriation that could be used to fund CSR payments—HHS directed CMS to discontinue CSR payments to issuers until Congress provides for an appropriation. As a result of this opinion, CMS discontinued CSR payments to issuers in the States operating a BHP (that is, New York and Minnesota). The States then sued the Secretary for declaratory and injunctive relief in the United States District Court for the Southern District of New York.¹⁰ On May 2, 2018, the parties filed a stipulation requesting a stay of the litigation so that HHS could issue an administrative order revising the 2018 BHP payment methodology. After consideration of the States' comments on the administrative order revising the payment methodology, we issued a Final Administrative Order on August 24, 2018 (Final Administrative Order) setting forth the payment methodology that would apply to the 2018 BHP program year.

In the November 5, 2019 **Federal Register** (84 FR 59529) (hereinafter referred to as the November 2019 final BHP Payment Notice), we finalized the payment methodologies for BHP program years 2019 and 2020.¹¹ The 2019 payment methodology is the same payment methodology described in the Final Administrative Order. The 2020 payment methodology is the same methodology as the 2019 payment methodology with one additional adjustment to account for the impact of individuals selecting different metal tier level plans in the Exchange, referred to as the Metal Tier Selection Factor

⁹ Sessions, J. (2017, Oct. 11). *Legal Opinion Re: Payments to Issuers for Cost Sharing Reductions (CSRs)*. Office of the Attorney General. <https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf>.

¹⁰ See *New York v. U.S. Dep't of Health & Human Servs.*, No. 18-cv-00683 (RJS) (S.D.N.Y. filed Jan. 26, 2018).

¹¹ BHP program year means a calendar year for which a standard health plan provides coverage for BHP enrollees. See 42 CFR 600.5.

(MTSF).¹² In the August 13, 2020 **Federal Register** (85 FR 49264) (hereinafter referred to as the August 2020 final BHP Payment Notice), we finalized the payment methodology for BHP program year 2021. The 2021 payment methodology is the same methodology as the 2020 payment methodology, with one adjustment to the income reconciliation factor (IRF). In the July 7, 2021 **Federal Register** (86 FR 35615) (hereinafter referred to as the July 2021 final BHP Payment Notice), we finalized the payment methodology for BHP program year 2022. The 2022 payment methodology is the same as the 2021 payment methodology, with the exception of the removal of the Metal Tier Selection Factor.

In the December 20, 2022 **Federal Register** (87 FR 77722) (hereafter referred to as the 2023 final BHP Payment Notice), we finalized the payment methodology for BHP program year 2023. The 2023 payment methodology is the same as the 2022 payment methodology, except for the addition of a factor to account for a State operating a BHP and implementing an approved State Innovation Waiver under section 1332 of the ACA; this is the section 1332 waiver factor (WF). In the 2023 final BHP Payment Notice (87 FR 77723), we also revised the schedule for issuance of payment notices and allowed payment notices to be effective for 1 or multiple program years, as determined by and subject to the direction of the Secretary, beginning with the 2023 payment methodology. In the 2025 Payment Notice, issued in the April 15, 2024 **Federal Register** (89 FR 26218), we finalized that States may start BHP applicants' effective date of eligibility on the first day of the month following the date of application. In addition, we finalized that, subject to HHS approval, a State may establish its own effective date of eligibility for enrollment policy.

B. Summary of Major Provisions

The regulations outlined in this proposed rule would be codified in 42 CFR part 600 and 45 CFR parts 153, 155, 156, and 158.

1. 42 CFR Part 600

We are proposing changes to the methodology regarding the premium adjustment factor (PAF), which is used to calculate the adjusted reference

premium (ARP) for BHP payment. We propose maintaining the PAF value at 1.188 for States that have fully implemented BHP and are using Second Lowest Cost Silver Plan (SLCSP) premiums from a year in which BHP was fully implemented. As previously clarified, for States in their first year of implementing BHP and choosing to use prior year SLCSP premiums to determine BHP payment, the PAF value would be set to 1.00. We propose that if a State is using SLCSP premiums from a year in which BHP was not fully implemented, the PAF is calculated by determining the CSR adjustment that QHP issuers included in the SLCSP premiums, reporting the CSR adjustments for the SLCSP for each region in the State to CMS, and then CMS calculating the PAF as 1.20 divided by 1 plus the adjustment. Additionally, we are proposing a technical clarification for BHP payment rates in cases of multiple SLCSP premiums in an area.

2. 45 CFR Part 153

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2025, the HHS-operated risk adjustment program is subject to the fiscal year 2025 sequestration.¹³ Therefore, the HHS-operated risk adjustment program will sequester payments made from fiscal year 2025 resources (that is, funds collected during the 2025 fiscal year) at a rate of 5.7 percent.

We propose to recalibrate the 2026 benefit year HHS risk adjustment models using the 2020, 2021, and 2022 benefit year enrollee-level EDGE data. Starting with the 2026 benefit year, we propose to begin phasing out the market pricing adjustment to the plan liability associated with Hepatitis C drugs in the HHS risk adjustment models (see, for example, 84 FR 17463 through 17466). We also are proposing to incorporate pre-exposure prophylaxis (PrEP) as a separate, new type of factor called an Affiliated Cost Factor (ACF) in the HHS risk adjustment adult and child models starting with the 2026 benefit year. We also request information on whether the HHS-operated risk adjustment program should take into account the time value of money for the collection and remittance of State transfers that occur 8 to 10 months after the conclusion of the benefit year. We also propose a risk adjustment user fee for the 2026 benefit

year of \$0.18 per member per month (PMPM).

Beginning with the 2025 benefit year of HHS–RADV, we propose to exclude enrollees without HCCs, which includes enrollees with only prescription drug categories (RXC), from the IVA sample, remove the Finite Population Correction (FPC) from the IVA sampling methodology, and replace the source of the Neyman allocation data used for HHS–RADV sampling with the most recent 3 years of consecutive HHS–RADV data. In addition, beginning with the 2024 benefit year of HHS–RADV, we propose to modify the SVA pairwise means test, which tests for statistical differences between the IVA and SVA results, to use a bootstrapped 90 percent confidence interval methodology and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees.

3. 45 CFR Part 155

We seek comment on how assisters who perform their assister duties in a hospital and hospital system may, within the bounds of the statute, refer consumers to programs designed to reduce medical debt.

We address our authority to investigate and undertake compliance reviews and enforcement actions in response to misconduct or noncompliance with applicable agent, broker, and web-broker Exchange requirements or standards occurring at the insurance agency level and how we intend to hold lead agents of insurance agencies accountable for such misconduct or noncompliance.

We propose to revise § 155.220(k)(3) to reflect our authority to suspend an agent's or broker's ability to transact information with the Exchange in instances where HHS discovers circumstances that pose unacceptable risk to accuracy of Exchange eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) and the privacy and security standards under § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction.

We propose to update the Model Consent Form that agents, brokers, and web-brokers can use to obtain and document consumer consent.¹⁴ The

¹² "Metal tiers" refer to the different actuarial value plan levels offered on the Exchanges. Bronze-level plans generally must provide 60 percent actuarial value; silver-level 70 percent actuarial value; gold-level 80 percent actuarial value; and platinum-level 90 percent actuarial value. See 45 CFR 156.140.

¹³ OMB. (2024). OMB Report to the Congress on the BBEDCA 251A Sequestration for Fiscal Year 2025. https://www.whitehouse.gov/wp-content/uploads/2024/03/BBEDCA_251A_Sequestration_Report_FY2025.pdf.

¹⁴ CMS. (2022, December 14). *CMS Model Consent Form for Marketplace Agents and Brokers*. PRA package (CMS–10840, OMB 0938–1438).

updates would expand the resource to include a standardized form that agents, brokers, and web-brokers can use to document the consumer's review and confirmation of the accuracy of information in their Exchange eligibility application, which is a new standard of conduct that was also implemented as part of the 2024 Payment Notice (88 FR 25809 through 25814). The proposed updates would also add scripts that agents, brokers, and web-brokers could utilize to meet the consumer consent and eligibility application review requirements finalized in the 2024 Payment Notice via an audio recording. We are not proposing any regulatory text changes since the use of the updated Model Consent Form would not be mandatory.

We propose to amend § 155.305(f)(4) to require Exchanges to provide notice to consumers and tax filers who have failed to file and reconcile their APTC for 2 consecutive years.

We propose to add § 155.400(d)(1) to codify HHS' guidance that requires that, within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in an State Exchange that includes a description of an inaccuracy that meets the requirements at § 156.1210(a)–(c) and all the information that the State Exchange requires or requests to properly assess the inaccuracy, State Exchanges must review and resolve the State Exchange issuer's enrollment data inaccuracies and submit to HHS a description of the resolution of any inaccuracies described by the State Exchange issuer that the State Exchange confirms to be inaccuracies in a format and manner specified by HHS.

We propose to revise § 155.400(g) to allow issuers to adopt a fixed-dollar payment threshold of \$5 or less, adjusted for inflation, under which issuers would not be required to trigger a grace period or terminate enrollment for enrollees who fail to pay the full amount of their portion of premium owed. We propose to limit application of this fixed-dollar payment threshold to premium payments after coverage is effectuated. Issuers would be required to apply the fixed-dollar threshold uniformly to all enrollees and without regard to their health status. Issuers would be allowed to apply either the fixed-dollar payment threshold or one of two percentage-based thresholds (one of which is currently permitted under § 155.400(g), but which we propose to modify).

We propose revisions to § 155.505(b) to codify an option for application filers to file appeals on behalf of applicants and enrollees on the application filer's Exchange application, as this would streamline the appeals process and ensure operational consistency between the FFEs and the HHS appeals entity or State Exchange appeals entity.

We propose to amend § 155.1000 to state explicitly that an Exchange may deny certification to any plan that does not meet the general certification criteria at § 155.1000(c). We also propose to amend § 155.1090 with refinements to the standards for a request for the reconsideration of a denial of certification specific to the FFEs.

We propose that in addition to collecting the information and data currently provided by Exchanges under § 155.1200 to monitor performance and compliance, we would use the information and data that Exchanges submit to increase transparency into Exchange operations and to promote program improvements. We anticipate publicly releasing the Exchanges annual State-based Marketplace Annual Reporting Tools (SMARTs), programmatic and financial audits, Blueprint applications, and additional data points in the Open Enrollment (OE) Data Reports. We are seeking input on how to best display these data points and how to best develop a performance measurement tool to assess Exchange quality and consumer experience.

4. 45 CFR Part 156

We solicit comments on reducing the risk of issuer insolvencies adversely impacting the integrity of the FFEs.

We propose 2026 benefit year FFE and SBE–FP user fee rates of 2.5 percent and 2.0 percent of total monthly premiums, respectively. However, if the enhanced PTC subsidies as currently enacted¹⁵ or at a higher level are extended through the 2026 benefit year by March 31, 2025, we propose a 2026 benefit year FFE user fee rate range between 1.8 and 2.2 percent of total monthly premiums and a 2026 benefit year SBE–FP user fee rate range between 1.4 and 1.8 of total monthly premiums, with each of these ranges to be set at a single rate in the final rule.

We affirm that certain CSR loading practices that are permitted by State regulators are permissible under Federal law to the extent that they are reasonable and actuarially justified. We

seek comment on whether we should codify this guidance at § 156.80(d).

We intend to revise the method for updating the AV Calculator, starting with the 2026 AV Calculator. Under this approach, for a plan year, we would only release a single, final version of the AV Calculator. We would also solicit public comments on the AV Calculator for a plan year generally but would only plan to incorporate this feedback into the development and release of the following plan year's AV Calculator.

We propose to make minor updates to the standardized plan option designs for PY 2026 to ensure these plans continue to have AVs within the permissible *de minimis* range for each metal level and to maintain a high degree of continuity with the approaches to standardized plan options finalized in the 2023, 2024, and 2025 Payment Notices. In addition, we propose to amend § 156.201 to require issuers that offer multiple standardized plan options within the same product network type, metal level, and service area to meaningfully differentiate these plans from one another in terms of included benefits, provider networks, and/or formularies.

We propose to amend § 156.202(b) and (d) to properly reflect the flexibility that issuers have been operationally permitted since these requirements were introduced to vary the inclusion of the distinct adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage categories under the non-standardized plan option limit in accordance with § 156.202(c)(1) through (3).

We propose to conduct ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions, beginning in PY 2026.

We propose to share aggregated, summary-level QIS information publicly on an annual basis beginning on January 1, 2026, with information QHP issuers submit during the PY 2025 QHP Application Period.

We propose to amend § 156.1220(a) to introduce a new materiality threshold for HHS–RADV appeals, such that HHS would rerun HHS–RADV results and adjust HHS–RADV adjustments to State transfers in response to a successful appeal when the impact of that appeal to the filer's HHS–RADV adjustments to State transfers is greater than or equal to \$10,000.

5. 45 CFR Part 158

We propose to amend § 158.140(b)(4)(ii) to allow qualifying issuers to not adjust incurred claims by the net payments or receipts related to

<https://www.cms.gov/files/document/cms-model-consent-form-marketplace-agents-and-brokers.pdf>.

¹⁵ ARP, Public Law 117–2 (2021). These enhanced subsidies were extended under the IRA, Public Law 117–169 (2022) and are scheduled to expire after the 2025 calendar year.

the risk adjustment program for MLR reporting and rebate calculation purposes beginning with the 2026 MLR reporting year (MLR reports due in 2027). We propose that for qualifying issuers, earned premium would account for net risk adjustment receipts by simply adding these net receipts to total premium, without subsequently subtracting them from adjusted earned premium, such that these net receipts would impact the MLR denominator rather than MLR numerator. We propose to amend § 158.103 to add a definition of “qualifying issuer.”

We also propose amendments to § 158.240(c) to add an illustrative example of how qualifying issuers would calculate the amount of rebate owed to each enrollee to accurately reflect how such issuers would incorporate the net risk adjustment transfer amounts into the MLR and rebate calculations differently from other issuers, as well as a conforming amendment to clarify that the current illustrative example in paragraph (c)(2) would apply to issuers that are not qualifying issuers.

III. Provisions of the Proposed Regulations

A. 42 CFR Part 600 BHP Methodology Regarding the Value of the Premium Adjustment Factor (PAF)

1. Overview of the Payment Methodology and Calculation of the Payment Amount

Section 1331(d)(3) of the ACA directs the Secretary to consider several factors when determining the Federal BHP payment amount, which, as specified in the statute, must equal 95 percent of the value of the PTC under section 36B of the Code and CSRs under section 1402 of the ACA that would have been paid on behalf of BHP enrollees had they enrolled in a QHP through an Exchange. Thus, the BHP payment methodology is designed to calculate the PTC and CSRs as consistently as possible and in general alignment with the methodology used by Exchanges to calculate advance payments of the PTC (APTC) and CSRs, and the methodology used to reconcile APTC with the amount of the PTC allowed for the tax year under section 36B of the Code. In accordance with section 1331(d)(3)(A)(iii) of the ACA, the final payment methodology must be certified by the Chief Actuary of CMS, in consultation with the Office of Tax Analysis (OTA) of the Department of the Treasury, as having met the requirements of section 1331(d)(3)(A)(ii) of the ACA.

Section 1331(d)(3)(A)(ii) of the ACA specifies that the payment

determination shall take into account all relevant factors necessary to determine the value of the PTC and CSRs that would have been paid on behalf of eligible individuals, including but not limited to, the age and income of the enrollee, whether the enrollment is for self-only or family coverage, geographic differences in average spending for health care across rating areas, the health status of the enrollee for purposes of determining risk adjustment payments and reinsurance payments that would have been made if the enrollee had enrolled in a QHP through an Exchange, and whether any reconciliation of APTC and CSR would have occurred if the enrollee had been enrolled. Under all previous payment methodologies, the total Federal BHP payment amount has been calculated using multiple rate cells in each BHP State. Each rate cell represents a unique combination of age range (if applicable), geographic area, coverage category (for example, self-only or two-adult coverage through the BHP), household size, and income range as a percentage of FPL, and there is a distinct rate cell for individuals in each coverage category within a particular age range who reside in a specific geographic area and are in households of the same size and income range. The BHP payment rates developed are also consistent with the State's rules on age rating. Thus, in the case of a State that does not use age as a rating factor on an Exchange, the BHP payment rates would not vary by age.

Under the methodology finalized in the July 2021 final BHP Payment Notice, the rate for each rate cell is calculated in 2 parts. The first part is equal to 95 percent of the estimated PTC that would have been allowed if a BHP enrollee in that rate cell had instead enrolled in a QHP in an Exchange. The second part is equal to 95 percent of the estimated CSR payment that would have been made if a BHP enrollee in that rate cell had instead enrolled in a QHP in an Exchange. These two parts are added together and the total rate for that rate cell would be equal to the sum of the PTC and CSR rates. As noted in the July 2021 final BHP Payment Notice, we currently assign a value of zero to the CSR portion of the BHP payment rate calculation, because there is presently no available appropriation from which we can make the CSR portion of any BHP payment.

The 2023 final BHP Payment Notice provides a detailed description of the structure of the BHP payments, including the equations, factors, and the values of the factors used to calculate the BHP payments. We are proposing one change to the methodology

regarding the premium adjustment factor (PAF).

The PAF is used to calculate the adjusted reference premium (ARP) that is used to calculate the BHP payment. The adjusted reference premium (ARP) is used to calculate the estimated PTC that would be allowed if BHP-eligible individuals enrolled in QHPs through an Exchange and is based on the premiums for the applicable second lowest cost silver plan during the applicable plan year. The PAF considers the premium increases in other States that took effect after we discontinued payments to issuers for CSRs provided to enrollees in QHPs offered through Exchanges. Despite the discontinuance of Federal payments for CSRs, QHP issuers are required to provide CSRs to eligible enrollees. As a result, many QHP issuers increased the silver-level plan premiums to account for those additional costs; these premium adjustments and how they were applied (for example, to only silver-level plans or to all metal tier plans) varied across States. For the States operating BHPs in 2018, the increases in premiums were relatively minor, because the majority of enrollees eligible for CSRs (and all who were eligible for the largest CSRs) were enrolled in the BHP and not in QHPs on the Exchanges, and therefore issuers in BHP States did not significantly raise premiums to cover costs related to HHS not making CSR payments.

In the Final Administrative Order and the 2019 through 2023 final BHP Payment Notices, we incorporated the PAF into the BHP payment methodologies to capture the impact of how other States responded to HHS ceasing to make CSR payments.¹⁶ We also reserved the right that in the case an appropriation for CSR payments is made for a future year, we would determine whether and how to modify the PAF in the payment methodology.

Under the Final Administrative Order, we calculated the PAF by using information sought from QHP issuers in each State and the District of Columbia and determined the premium adjustment that the responding QHP issuers made to each silver level plan in 2018 to account for the discontinuation of CSR payments to QHP issuers. Based on the data collected, we estimated the median adjustment for silver level QHPs nationwide (excluding those in the two BHP States). To the extent that QHP issuers made no adjustment (or the adjustment was zero), this was counted as zero in determining the median

¹⁶ <https://www.medicaid.gov/sites/default/files/2019-11/final-admin-order-2018-revised-payment-methodology.pdf>.

adjustment made to all silver level QHPs nationwide. If the amount of the adjustment was unknown—or we determined that it should be excluded for methodological reasons (for example, the adjustment was negative, an outlier, or unreasonable)—then we did not count the adjustment towards determining the median adjustment.¹⁷ The median adjustment for silver level QHPs is referred to as the nationwide median adjustment.

For each of the two BHP States, we determined the median premium adjustment for all silver level QHPs in that State, which we refer to as the State median adjustment. The PAF for each BHP State equaled one plus the nationwide median adjustment divided by one plus the State median adjustment for the BHP State. In other words,

$$PAF = (1 + \text{Nationwide Median Adjustment}) \div (1 + \text{State Median Adjustment}).$$

To determine the PAF described above, we sought to collect QHP information from QHP issuers in each State and the District of Columbia to determine the premium adjustment those issuers made to each silver level plan offered through the Exchange in 2018 to account for the end of CSR payments. Specifically, we sought information showing the percentage change that QHP issuers made to the premium for each of their silver level plans to cover benefit expenditures associated with the CSRs, given the lack of CSR payments in 2018. This percentage change was a portion of the overall premium increase from 2017 to 2018.

According to our 2018 records, there were 1,233 silver-level QHPs operating on Exchanges in 2018. Of these 1,233 QHPs, 318 QHPs (25.8 percent) responded to our request for the percentage adjustment applied to silver-level QHP premiums in 2018 to account for the discontinuance of HHS making CSR payments. These 318 QHPs operated in 26 different States, with 10 of those States running State Exchanges (while we requested information only from QHP issuers in States serviced by an FFE, many of those issuers also had QHPs in State Exchanges and submitted information for those States as well). Thirteen of these 318 QHPs were in New York (and none were in Minnesota). Excluding these 13 QHPs

from the analysis, the nationwide median adjustment was 20.0 percent. Of the 13 QHPs in New York that responded, the State median adjustment was 1.0 percent. We believed that this was an appropriate adjustment for QHPs in Minnesota, as well, based on the observed changes in New York's QHP premiums in response to the discontinuance of CSR payments (and the operation of the BHP in that State) and our analysis of expected QHP premium adjustments for States with BHPs. We calculated the proposed PAF as $(1 + 20\%) \div (1 + 1\%)$ (or $1.20/1.01$), which results in a value of 1.188.

We set the value of the PAF to 1.188 for all program years for 2018 through 2024, with limited exceptions.¹⁸ We believe that this value for the PAF continues to reasonably account for the increase in silver-level premiums experienced in non-BHP States that took effect after the discontinuance of the CSR payments.

Starting in 2023, we made one limited exception in setting the value of the PAF as part of the 2023 final BHP Payment Notice.¹⁹ In the case of a State in the first year of implementing a BHP, if the State chooses to use prior year second lowest cost silver plan (SLCSP) premiums to determine the BHP payment (for example, the 2025 premiums for the 2026 program year), we set the value of the PAF to 1.00. In this case, we believe that adjustment to the QHP premiums to account for the discontinuation of CSR payments would be included fully in the prior year premiums, and no further adjustment would be necessary.

We propose to make a change to the calculation of the PAF starting in program year 2026. There are cases in which a State may not have fully implemented BHP for a full program year. For example, a State may operate BHP for only a portion of the year (in other words, less than 12 months); there may be other such cases in which a State would be deemed to have partially implemented BHP for a program year.

For a State that initially only partially implemented BHP, it is likely that, in the year (or years) when the BHP is only partially implemented, the percentage adjustment to the premiums for the program year to account for the discontinuation of CSR payments may be significantly higher than the 1 percent adjustment we determined for BHP States in 2018. In these cases, it is probable that QHP issuers would include a larger premium adjustment (that is, greater than 1 percent) because

more individuals would be eligible for CSRs (and individuals eligible for relatively larger CSRs) would be enrolled in a QHP on the Exchange, for part or all of the initial implementation year. If premiums with a larger CSR adjustment are used as a basis for calculating the BHP payments and the current value of the PAF (1.188) is used, it is likely that this would “double count” a portion of the adjustment and lead to an effective CSR adjustment over 20 percent.

For example, assume a State implements BHP for only 6 months in a program year. As a result, QHP issuers may include a 10 percent adjustment to the premiums to account for the discontinuation of the CSR for the portion of the year when CSR eligible individuals would have QHP coverage. The issuers would be liable for roughly half of the CSR amounts they would have had to provide if there was no BHP in place. Under the previous BHP payment methodology, if these premiums that already partially account for CSRs are used to calculate the BHP payment, we would increase the reference premium by 18.8 percent for the PAF, leading to an effective increase of 30.68 percent (1.188 multiplied by 1.10 minus 1). This is significantly larger than the 20 percent adjustment we determined as the basis for the PAF for States that have operated their BHP for more than two full program years.

Under the Secretary's general authority to account for all relevant factors necessary to determine the value of the premium and cost-sharing reductions that would have been provided to eligible individuals now enrolled in BHP coverage²⁰ and to avoid such an overpayment, we propose the following changes to the PAF:

(1) If a State has fully implemented BHP and is using SLSCP premiums for a year in which the BHP was fully implemented, then the value of the PAF would remain 1.188, as described above.

(2) If a State is in the first year of implementing a BHP and the State chooses to use prior year SLSCP premiums to determine the BHP payment (for example, the 2025 premiums for the 2026 program year), we set the value of the PAF to 1.00. This is the same approach described in the 2023 final BHP Payment Notice.

(3) If a State is using SLSCP premiums from a year in which BHP was not fully implemented, then the PAF is calculated as follows:

First, the State must determine the CSR adjustment that QHP issuers included in the SLSCP premiums for individual

¹⁷ Some examples of outliers or unreasonable adjustments include (but are not limited to) values over 100 percent (implying the premiums doubled or more because of the adjustment), values more than double the otherwise highest adjustment, or non-numerical entries.

¹⁸ 87 FR 77731, 77737.

¹⁹ Id. at 77732.

²⁰ Section 1331(d)(3)(A)(ii) of the PHS Act.

market Exchange plans. The State should identify the SLSCP in each region, as defined for the Exchange. For each SLSCP, the State should determine the CSR adjustment that the QHP issuer included in the premium. This may be done by (1) reviewing any materials submitted by the QHP issuer describing the calculation of the premium; or (2) requesting that the QHP issuer provide the adjustment, or an estimate of the adjustment used in calculating the premium. Second, the State should report the CSR adjustments for the SLSCP for individual market Exchange plans for each region in the State to CMS. Third, CMS will take this percentage adjustment and calculate the PAF as 1.20 divided by 1 plus the adjustment. For example, if the percentage adjustment for the CSR is 5 percent, the PAF would be $(1.20 \div 1.05)$, or 1.143. The maximum value of the PAF would be 1.188, and the minimum value of the PAF would be 1.00.

This approach would apply based on the premium year, not necessarily the program year. If the State has fully implemented BHP but is using the prior year premiums and BHP was not fully implemented in that year, this modified approach would still apply. For example, if a State partially implemented BHP in 2026 and fully implemented BHP in 2027, when determining the BHP payments for 2027, we would then use 1.188 for the value of the PAF if the State elected to use 2027 QHP premiums to determine the payment; if the State elected to use the 2026 QHP premiums, then we would use the modified PAF calculation described in this section. CMS would make a determination of whether or not a BHP was fully implemented based on a review of the Blueprint and provide that determination to the State.

We considered other approaches to the modified PAF. We considered whether or not CMS would collect data on the underlying CSR adjustment in the SLSCP premiums; however, we believe that such activities fall within States' roles as BHP administrators and States are better able to work with QHP issuers to administer this data collection process. We also considered if States should survey all QHP issuers (not just those with the SLSCP premium). We believe that only using the CSR adjustment from individual market Exchange plans with the SLSCPs would be a more reasonable approach and would minimize the burden on States and QHP issuers by only requiring the State to work with one issuer in each region, as opposed to all issuers in each region. We also considered whether or

not we should make further changes to the PAF, but we believe that this approach balances maintaining accurate BHP payments with stability and limited burden for BHP States. We request comments on this approach or alternative approaches to calculating the PAF.

2. Technical Clarification for Calculation of BHP Payment Rates in Cases of Multiple Second Lowest Cost Silver Plan Premiums in an Area

The BHP payment rates are based on the second lowest cost silver plan premium among individual market QHPs operating on the Exchanges in each rating area (or county) in a State. This is the basis for the reference premium (or RP) in the BHP payment methodology.

In general, we expect that each county would have a unique second lowest cost silver plan premium, which is used to calculate the payment rates for residents of that county for the BHP payment. However, in some cases, we have found that States may have more than one second lowest cost silver plan within a county. This may occur in cases where the State has allowed QHPs to operate in only a portion of the county instead of the entire county on the Exchange.

In our previous BHP payment methodologies, we do not describe how such a case would be handled for calculating BHP payments. In our technical guidance to States, we have instructed States to report the premiums for the second lowest cost silver plan operating in the largest part of the county as measured by total population.

Under the Secretary's general authority to account for all relevant factors necessary to determine the value of the premium and cost-sharing reductions that would have been provided to eligible individuals now enrolled in BHP coverage,²¹ for the 2026 payment methodology and all subsequent years, we propose to clarify that in cases where there are more than one second lowest cost silver plans in a county, the BHP payment would be based on the premium of the second lowest cost silver plan applicable to the largest portion of the county as measured by total population. We welcome comments on this approach.

B. 45 CFR Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

In subparts A, B, D, G, and H of part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program

is a permanent program created by section 1343 of the ACA that transfers funds from issuers of lower-than-average risk, risk adjustment covered plans to issuers of higher-than-average risk, risk adjustment covered plans in the individual, small group markets, or merged markets, inside and outside the Exchanges. In accordance with § 153.310(a), a State that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program or have HHS do so on its behalf.²² HHS did not receive any requests from States to operate risk adjustment for the 2026 benefit year. Therefore, HHS will operate risk adjustment in every State and the District of Columbia for the 2026 benefit year.

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2025, the HHS-operated risk adjustment program is subject to the fiscal year 2025 sequestration.²³ The Federal government's 2025 fiscal year will begin on October 1, 2024. Therefore, the HHS-operated risk adjustment program will be sequestered at a rate of 5.7 percent for payments made from fiscal year 2025 resources (that is, funds collected during the 2025 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 (BBEDCA),²⁴ as amended, and the underlying authority for the HHS-operated risk adjustment program, the funds that are sequestered in fiscal year 2025 from the HHS-operated risk adjustment program will become available for payment to issuers in fiscal year 2026 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, the program would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

Additionally, we note that the Infrastructure Investment and Jobs Act²⁵ amended section 251A(6) of the BBEDCA and extended sequestration for the HHS-operated risk adjustment

²² See also 42 U.S.C. 18041(c)(1).

²³ OMB. (2024). OMB Report to the Congress on the BBEDCA 251A Sequestration for Fiscal Year 2025. https://www.whitehouse.gov/wp-content/uploads/2024/03/BBEDCA_251A_Sequestration_Report_FY2025.pdf.

²⁴ Public Law 99–177 (1985).

²⁵ Public Law 117–58, 135 Stat. 429 (2021).

²¹ Section 1331(d)(3)(A)(ii) of the PHS Act.

program through fiscal year 2031 at a rate of 5.7 percent per fiscal year.²⁶

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 State payment transfer formula²⁷ that is part of the HHS Federally certified risk adjustment methodology utilizes separate models for adults, children, and infants to account for clinical and cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year,²⁸ and prescription drug categories (RXC) beginning with the 2018 benefit year.²⁹ Starting with the 2023 benefit year, we removed the severity illness factors in the adult models and added interacted HCC count factors (that is, additional factors that express the presence of a severity or transplant HCC in combination with a specified number of total payment HCCs or HCC groups on the enrollee's record) to the adult and child models³⁰ applicable to certain severity and transplant HCCs.³¹

Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a

cost sharing reduction (CSR) adjustment factor. The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (also referred to as the plan liability risk score (PLRS)) within a geographic rating area is one of the inputs into the 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 for a given benefit year. 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 HHS Risk Adjustment Model Recalibration for the 2026 Benefit Year

We are proposing to recalibrate the 2026 benefit year HHS risk adjustment models with the 2020, 2021, and 2022 enrollee-level EDGE data. Consistent with the approach outlined in the 2020 Payment Notice, we propose to recalibrate the HHS risk adjustment models for the 2026 benefit year using only enrollee-level EDGE data, and to continue to use blended, or averaged, coefficients from the 3 years of separately solved models for the 2026 benefit year model recalibration.³² Additionally, as outlined in the 2022 Payment Notice (86 FR 24140, 24152), we propose to use the 3 most recent consecutive years of enrollee-level EDGE data that are available at the time we estimate the draft recalibrated coefficients published in the proposed rule for the applicable benefit year.³³ We believe this promotes stability, meets the goal of the HHS-operated risk adjustment program, and allows issuers more time to incorporate this information when pricing their plans for the upcoming benefit year.

In the 2024 Payment Notice (88 FR 25740 through 25749), we finalized the use of 2018, 2019 and 2020 benefit year enrollee-level EDGE data for recalibration of the 2024 benefit year HHS risk adjustment models for all model coefficients. As explained in the 2024 Payment Notice proposed rule (87 FR 78215 through 78216) and final rule (88 FR 25749 through 25753), we analyzed the 2020 benefit year data to identify possible impacts of the COVID-19 Public Health Emergency (PHE). Our analysis generally found that the 2020 enrollee-level EDGE data were

anomalous primarily in the volume and frequencies of certain types of claims, but that the relative costs of specific services, at least those associated with payment HCCs in the HHS risk adjustment models, were largely unaffected. Because the HHS risk adjustment models predict relative costs of care for specific conditions on an enrollee-level basis and tend not to rely on overall patterns of utilization, the minimal impacts to relative costs of care for payment HCCs likewise resulted in minimal impacts on the coefficients fitted by the 2020 enrollee-level EDGE recalibration data.

Then, in the 2025 Payment Notice (89 FR 26236 through 26238), we finalized the use of 2019, 2020 and 2021 benefit year enrollee-level EDGE data for recalibration of the 2025 benefit year HHS risk adjustment models for all model coefficients. As explained in the 2025 Payment Notice proposed rule (88 FR 82527 through 82529) and final rule (89 FR 26236 through 26238), we recognized that the COVID-19 PHE was still in effect throughout the 2021 benefit year.³⁴ Therefore, similar to our analysis of 2020 benefit year data to identify possible impacts of the COVID-19 PHE, we conducted additional analyses to determine whether any anomalies in the 2021 benefit year enrollee-level EDGE data were present beyond expected year-to-year variation and whether the use of 2 years of PHE-impacted data presented any additional concerns. Our analysis found that the coefficients for the 2021 benefit year enrollee-level EDGE recalibration data were similar to the 2019 and 2020 benefit year's coefficients, with levels of variation consistent with typical changes in coefficients for new years of data. We did not identify any significant anomalies and incorporated the 2021 benefit year enrollee-level EDGE data in the 2025 risk adjustment model recalibration without exception.

Consistent with the approach for use of 2020 and 2021 benefit year enrollee-level EDGE data, we performed reviews of the 2022 benefit year enrollee-level EDGE data to identify potential anomalies prior to incorporating the 2022 benefit year enrollee-level EDGE data as part of the proposed recalibration of the HHS risk adjustment models for the 2026 benefit year. Our review did not identify systematic anomalies in the 2022 enrollee-level EDGE data. Therefore, after considering our analysis of the 2020, 2021 and 2022

²⁶ 2 U.S.C. 901a.

²⁷ The State payment transfer formula refers to part of the Federally certified risk adjustment methodology that applies in States where HHS is responsible for operating the program. The formula calculates payments and charges at the State market risk pool level (prior to the calculation of the high-cost risk pool payment and charge terms that apply beginning with the 2018 benefit year). See, for example, 81 FR 94080.

²⁸ For the 2017 through 2022 benefit years, there is a set of 11 binary enrollment duration factors in the adult models that decrease monotonically from 1 to 11 months, reflecting the increased annualized costs associated with fewer months of enrollments. See, for example, 81 FR 94071 through 94074. These enrollment duration factors were replaced beginning with the 2023 benefit year with HCC-contingent enrollment duration factors for up to 6 months in the adult models. See, for example, 87 FR 27228 through 27230.

²⁹ 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 models. See, for example, 83 FR 16941.

³⁰ See table 4 for a list of factors in the adult models, and table 5 for a list of factors in the child models.

³¹ See 87 FR 27224 through 27228. Also see table 6 below.

³² 84 FR 17463 through 17466.

³³ Although we do receive the next year of enrollee-level EDGE data prior to the proposed rule, that data must go through several quality and analysis checks before it is useable for HHS risk adjustment model recalibration.

³⁴ See, for example, ASPR. (2023, February 9). Renewal of Determination that a Public Health Emergency Exists. <https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx>.

enrollee-level EDGE data, we propose to determine coefficients for the 2026 benefit year HHS risk adjustment models based on a blend of separately solved coefficients from the 2020, 2021, and 2022 benefit years' enrollee-level EDGE data, with the costs of services identified from the data trended between the relevant year of data and the 2026 benefit year.³⁵ The draft coefficients listed reflect the use of trended 2020, 2021, and 2022 benefit year enrollee-level EDGE data, as well as other HHS risk adjustment model updates proposed in this proposed rule (including, for example, the proposed phasing out of the pricing adjustment for Hepatitis C drugs).³⁶ However, we note that the draft coefficients could change between the proposed and final rule if we identify an error after publication of this proposed rule or if any proposed models are modified or not finalized in response to comments. In addition, consistent with § 153.320(b)(1)(i), if we are unable to finalize the final coefficients in time for publication in the final rule, we would publish the final coefficients for the 2026 benefit year in guidance soon after the publication of the final rule.

We seek comment on the proposal to determine 2026 benefit year coefficients for the HHS risk adjustment models based on a blend of separately solved coefficients from the 2020, 2021, and 2022 enrollee-level EDGE data.

³⁵ As described in the *2016 Risk Adjustment White Paper* (<https://www.cms.gov/ccio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf>) and the 2017 Payment Notice (81 FR 12218), we subdivide expenditures into traditional drugs, specialty drugs, medical services, and preventive services and determine trend factors separately for each category of expenditure. In determining these trend factors, we consult our actuarial experts, review relevant Unified Rate Review Template (URRT) submission data, analyze multiple years of enrollee-level EDGE data, and consult National Health Expenditure Accounts (NHEA) data as well as external reports and documents published by third parties. In this process, we aim to determine trends that reflect changes in cost of care rather than gross growth in expenditures. As such, we believe the trend factors we used for each expenditure category for the proposed 2026 benefit year models are appropriate for the most recent changes in cost of care that we have seen.

³⁶ Additionally, this rulemaking includes a proposal to incorporate pre-exposure prophylaxis (PrEP) into a separate model factor in the HHS risk adjustment adult and child models for the 2026 benefit year. Although a separate proposed PrEP risk adjustment model factor is not included in tables 4 through 9, we do provide a comprehensive analysis of our considerations and structure for including a separate PrEP risk adjustment model factor, including the impact of the proposed addition of a PrEP factor on other model factors in that section of this rulemaking.

b. Pricing Adjustment for the Hepatitis C Drugs

Beginning with the 2026 benefit year, we propose to begin phasing out the market pricing adjustment³⁷ to the plan liability associated with Hepatitis C drugs in the HHS risk adjustment models and start trending Hepatitis C drugs consistent with the other drugs³⁸ in the HHS risk adjustment models. Since the 2020 benefit year HHS risk adjustment models, we have included a market pricing adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing prior to solving for coefficients for the models.³⁹ The purpose of this market pricing adjustment was to account for significant pricing changes between the data years used for recalibrating the models and the applicable benefit year of risk adjustment as a result of the introduction of new and generic Hepatitis C drugs.⁴⁰ We have committed to annually reassessing the Hepatitis C pricing adjustment with additional years of enrollee-level EDGE data as the data becomes available.

As part of the 2026 benefit year model recalibration analysis, we reassessed the cost trend for Hepatitis C drugs using available enrollee-level EDGE data (including 2022 benefit year data) to consider whether the pricing adjustment was still needed and, if it is still needed, whether it should be modified. We found that projected costs for Hepatitis C drugs have begun to rise alongside the expected cost of other specialty drugs after many years of decline and stagnation due to the introduction of new and generic Hepatitis C drugs. Therefore, we believe that it is appropriate to begin phasing out the

³⁷ For discussion relating to the Hepatitis C Pricing Adjustment for previous benefit years, *see*, for example, 89 FR 26237 through 26238.

³⁸ *See* 81 FR 12218 through 12219.

³⁹ The Hepatitis C drugs market pricing adjustment to plan liability is applied for all enrollees taking Hepatitis C drugs in the data used for recalibration.

⁴⁰ *See* Milligan, J. (2018). A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV. Gilead. <https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv>. *See also* AbbVie. (2017). AbbVie Receives U.S. FDA Approval of MAVYRET™ (glecaprevir/pibrentasvir) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT 1–6) in as Short as 8 Weeks. AbbVie. <https://news.abbvie.com/news/abbvie-receives-us-fda-approval-mavyret-glecaprevir-pibrentasvir-for-treatment-chronic-hepatitis-c-in-all-major-genotypes-gt-1-6-in-as-short-as-8-weeks.htm>. *See also* Silseth, S., & Shaw, H. (2021). Analysis of prescription drugs for the treatment of hepatitis C in the United States [White paper]. Milliman. <https://www.milliman.com/-/media/milliman/pdfs/2021-articles/6-11-21-analysis-prescription-drugs-treatment-hepatitis-c-us.ashx>.

market pricing adjustment for Hepatitis C drugs and start trending the cost of these drugs consistent with other similar drugs in the HHS risk adjustment models to ensure that we continue to use the most appropriate estimates of the average cost of Hepatitis C treatments for recalibration of the HHS risk adjustment models for the 2026 benefit year and beyond.

To explain further, because the annual recalibration of our risk adjustment models use the most recent 3 years of enrollee-level EDGE data available at the time of the proposed rule (in the case of this proposed rule and the recalibration of the 2026 benefit year models: the 2020, 2021, and 2022 enrollee-level EDGE data) in our simulation of plan liability for the applicable benefit year, we apply trend factors to different categories of medical expenditures, including specialty drugs, for every calendar year between the applicable benefit year and each year of enrollee-level EDGE data.^{41 42} For example, to project costs for 2026 benefit year risk adjustment, we trend the 2020 enrollee-level EDGE data forward 6 years, the 2021 enrollee-level EDGE data forward 5 years, and the 2022 enrollee-level EDGE data forward 4 years. We have previously developed the Hepatitis C market pricing adjustment by applying a separate annual trend factor to Hepatitis C drugs in lieu of applying the annual specialty drug trend we apply to all other specialty drugs. The intent of this adjustment is to track the projected decrease and stagnation of Hepatitis C drug prices due to the introduction of new and generic versions of Hepatitis C drugs as identified in various sources of available market data⁴³ and through consultation with our actuarial experts. As illustrated by table 1, this proposal would continue to trend Hepatitis C drugs separately from specialty drugs to project decrease and stagnation of Hepatitis C treatment pricing changes

⁴¹ *See*, *supra*, notes 38 and 39.

⁴² Because EDGE data do not generally account for drug rebates per the EDGE Business Rules (available at https://regtap.cms.gov/reg_library.php?i=3765), for the purposes of risk adjustment recalibration, we also incorporate assumptions about the incidence of drug rebates in our trending of prescription drug data.

⁴³ *See* 88 FR 25753–25754. *See also*, Silseth, S., & Shaw, H. (2021). *Analysis of prescription drugs for the treatment of Hepatitis C in the United States*. Milliman White Paper. <https://www.milliman.com/-/media/milliman/pdfs/2021-articles/6-11-21-analysis-prescription-drugs-treatment-hepatitis-c-us.ashx>. *See also*, Cline, M., Schweitzer, K., Silseth, S., & Wang, M. (2021). *Projected U.S. national hepatitis C treatment costs and estimated reduction to medical costs*. Milliman White Paper. <https://www.milliman.com/-/media/milliman/pdfs/2021-articles/9-22-21-hcv-treatment-and-medical-cost-whitepaper.ashx>. *See also*, *supra*, note 35.

between 2020 and 2021 (for the 2020 EDGE data), between 2021 and 2022 (for the 2020 and 2021 EDGE data), and between 2022 and 2023, between 2023 and 2024, and between 2024 and 2025 for all three data years (2020, 2021, and 2022 EDGE data) used for recalibration of the 2026 benefit year HHS risk adjustment models. Once we have trended Hepatitis C costs to reflect no growth from the 2020, 2021, and 2022 enrollee-level EDGE data to the 2025 benefit year, under this proposal for 2026 benefit year risk adjustment, we would complete the trending of these 3 years of data from the 2025 benefit year to the 2026 benefit year by applying the specialty drug trend factor, rather than the Hepatitis C trend factor that reflects the unique market pricing adjustment for these drugs.

In other words, we propose to adopt a phased approach (See table 1) to transition the Hepatitis C drugs' trending as part of the annual recalibration of the HHS risk adjustment models beginning with the 2026 benefit year to move away from the current unique market pricing adjustment for these drugs and align with the trending approach for specialty drugs as we expect that the current growth in Hepatitis C drug costs will continue to be similar to growth in specialty drug costs in future years. As described above, to begin this transition for the 2026 benefit year HHS risk adjustment models, we propose to apply the

specialty drug trend to 1 year of trending Hepatitis C treatment costs (that is, the trend from 2025 to 2026) for all 3 years of enrollee-level EDGE data used in recalibration (that is, 2020, 2021, and 2022 enrollee-level EDGE data). These 3 years of enrollee-level EDGE data would otherwise be trended forward using the lower trend rate reflecting the market pricing adjustment for Hepatitis C treatments through the 2025 benefit year. As such, 2026 benefit year recalibration data for Hepatitis C would reflect 1 year of growth in the cost of treatment at the same rate as other specialty drugs. To continue the transition of phasing out the Hepatitis C drug pricing adjustment in future benefit years' annual model recalibration, under this proposal, we would annually increase the number of years for which we would use the specialty drug trend and decrease the number of years that would use the unique market pricing adjustment for Hepatitis C drugs. For example, as seen in table 1, for the recalibration of the 2027 benefit year HHS risk adjustment models, under this proposal, we would apply the specialty drug trend to 2 years of the trending used in the models to project growth in Hepatitis C drugs. Specifically, assuming that the 2027 benefit year would use 2021, 2022, and 2023 enrollee-level EDGE data for the annual model recalibration, we would project Hepatitis C treatment pricing

changes reflecting the unique market pricing adjustment between 2021 and 2022 (for the 2021 EDGE data), between 2022 and 2023 (for the 2021 and 2022 EDGE data), and between 2023 and 2024 and between 2024 and 2025 for all three data years (2021, 2022, and 2023 EDGE data) used for the recalibration of the 2027 benefit year HHS risk adjustment models. Again, once we have trended Hepatitis C drug costs to reflect the unique market pricing adjustment from the 2021, 2022, and 2023 enrollee-level EDGE data to the 2025 benefit year, under the proposed transitional approach, for recalibration of the 2027 benefit year HHS risk adjustment models, we would complete the trending of these 3 years of data from the 2025 benefit year to the 2027 benefit year by applying the specialty drug trend factor between the 2025 and 2026 benefit years and between the 2026 and 2027 benefit years. This approach would continue until such time as all enrollee-level EDGE data years used for the recalibration of the HHS risk adjustment models are from benefit year 2025 or later (See table 1), at which time the specialty drug cost trend would be fully applied to Hepatitis C drug costs consistent with other specialty drugs in the HHS risk adjustment models and we would stop applying the separate market pricing adjustment for Hepatitis C drugs as part of the annual model recalibration.

TABLE 1: Proposed Transition of the Hepatitis C Market Pricing Adjustment (Hep C Trend) to the Specialty Drug Trend for HHS Risk Adjustment Model Recalibration

Year of EDGE Data	Year-to-Year Trend Rate Used								
	2020- 2021	2021- 2022	2022- 2023	2023- 2024	2024- 2025	2025- 2026	2026- 2027	2027- 2028	2028- 2029
2020 Data Year	Hep C Trend	Hep C Trend	Hep C Trend	Hep C Trend	Hep C Trend	Specialty Drug Trend	--*	--*	--*
2021 Data Year	--	Hep C Trend	Hep C Trend	Hep C Trend	Hep C Trend	Specialty Drug Trend	Specialty Drug Trend	--*	--*
2022 Data Year	--	--	Hep C Trend	Hep C Trend	Hep C Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend	--*
2023 Data Year	--	--	--	Hep C Trend	Hep C Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend
2024 Data Year	--	--	--	--	Hep C Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend
2025 Data Year	--	--	--	--	--	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend

*Data year projected to no longer be used for the applicable benefit year recalibration

We propose this transitional approach because we continue to believe a market pricing adjustment specific to Hepatitis C drugs in the simulation of plan liability as part of the annual recalibration of the HHS risk adjustment models for benefit years that involve the use of enrollee-level EDGE data prior to 2025 (for example, for 2026 recalibration, the 2020 through 2022 enrollee-level EDGE data, and the 2023 through 2025 intermediate years of trending) is necessary and appropriate to account for the lack of growth in Hepatitis C drug prices relative to other prescription drugs in the market between those data years and the 2025 benefit year.

We seek comment on our proposal to phase out the market pricing adjustment and trend Hepatitis C drugs consistent with other specialty drugs starting with the annual recalibration of the 2026 benefit year HHS risk adjustment models.

c. Proposed Inclusion of Pre-Exposure Prophylaxis (PrEP) in the HHS Risk Adjustment Adult and Child Models as an Affiliated Cost Factor (ACF)

We are proposing to incorporate human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) as a

separate, new type of factor called an Affiliated Cost Factor (ACF) in the HHS risk adjustment adult and child models starting with the 2026 benefit year. This proposed change would reflect an evolution in our approach to defining the factors used in the HHS risk adjustment models to include a factor that is not indicative of an active condition and would change our current policy that models the costs of PrEP alongside all other preventive services.

Starting with the 2021 benefit year HHS risk adjustment models, as finalized in the 2021 Payment Notice (85 FR 29185 through 29187), we incorporated PrEP in the simulation of plan liability in the HHS risk adjustment adult and child models as a preventive service with zero cost sharing after careful analysis of preventive drugs that are recommended at grade A or B by the United States Preventive Services Task Force (USPSTF), including analysis on when PrEP can be used as a preventive service.⁴⁴ Specifically, in June 2019, the USPSTF recommended the use of PrEP as a preventive service for persons who are

at high risk of HIV acquisition.⁴⁵ Because Section 2713 of the PHS Act, as added by Section 1001 of the ACA, requires that non-grandfathered group health plans and health insurance issuers in the group and individual markets cover certain recommended preventive services without imposing cost sharing,⁴⁶ we modified the

⁴⁵ See US Preventive Services Task Force. *Preexposure prophylaxis for the prevention of HIV infection: US Preventive Services Task Force recommendation statement.* *JAMA.* 2019;321(22):2203–2213. The USPSTF issued an updated recommendation on August 22, 2023. The updated recommendation is available at <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

⁴⁶ On March 30, 2023, the United States District Court for the Northern District of Texas issued a final judgment in the case *Braidwood Management Inc. v. Becerra*, Civil Action No. 4:20-cv-00283-O (N.D. Tex. Mar. 30, 2023) holding that the USPSTF's recommendations operating in conjunction with PHS Act section 2713(a)(1) violate the Appointments Clause of Article II of the United States Constitution and are therefore unlawful. On appeal, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court on the merits but held that prospective and retrospective relief was limited to the named plaintiffs. The case was remanded to the District Court for further proceedings. On August 28, 2024, based on the Defendants' intent to file a petition for writ of certiorari by September 19, 2024, the District Court

⁴⁴ See 85 FR 29185 through 29187.

simulation of plan liability as part of the annual recalibration of the HHS risk adjustment adult and child models to account for the higher level of cost sharing associated with its status as a preventive service, similar to how we treat other preventive services.

As a general principle, we currently incorporate preventive services into each of the HHS risk adjustment models to ensure that 100 percent of the cost of those services are reflected in the simulation of plan liability. In the simulation of plan liability, services are only counted as preventive when they occur in the recommended circumstances (for example, age) to the extent we can identify such circumstances from enrollee-level EDGE data. As with other preventive services, the incorporation of PrEP into the simulation of plan liability as a preventive service tends to impact the age-sex coefficients for the population that is most likely to utilize the given preventive service. For PrEP, this population is typically males between the ages of 25 and 39, because this group composes the most frequent utilizers of PrEP in the enrollee-level EDGE data. In addition to PrEP drugs, like other preventive services,⁴⁷ ancillary services related to PrEP care (for example, HIV screenings) qualify as preventive services and as such are also currently calibrated at 100 percent plan liability in the recalibration of the HHS risk adjustment adult and child models.⁴⁸

However, as a part of our commitment to consider ways to continually improve the HHS risk adjustment models, we continued to monitor and assess different ways to incorporate PrEP in the HHS risk adjustment models. In this regard, since the adoption of the current approach beginning with the 2021 benefit year HHS risk adjustment adult and child models, we have continued to assess the incorporation of PrEP into these models as we do other preventive services. We have also continued to receive recommendations from some interested parties that PrEP be incorporated into the HHS risk

adjustment adult models differently than other preventive services in the calculation of plan liability due to the high cost of PrEP. We previously considered changing the treatment of PrEP to incorporate it in the HHS risk adjustment adult models as an RXC; however, we have always been concerned with this approach because RXCs are specifically incorporated as separate factors to impute a missing diagnosis or indicate severity of a diagnosis.⁴⁹ As such, we did not incorporate PrEP into RXC 1 (Anti-HIV Agents) because PrEP utilization does not indicate an HIV/AIDS diagnosis or the severity of a diagnosis. We also considered incorporating the use of PrEP in the HHS risk adjustment models as a separate HCC, but we did not believe that approach would be appropriate because the principles for including an HCC into the models require that each HCC represents well-specified, clinically significant, chronic or systematic medical conditions.⁵⁰ Because there is no active chronic medical condition involved, the use of PrEP for prevention of an HIV infection does not satisfy these criteria either.

Additionally, when we initially incorporated PrEP as a preventive service in the simulation of plan liability in the HHS risk adjustment adult and child models, we expected that any risk of adverse selection regarding PrEP would decrease over time as we expected the costs of PrEP to decrease due to generics entering the market and gaining market share. We also expected minimal differences in issuers' populations of PrEP users because, under Section 2713 of the PHS Act and its implementing regulations at 45 CFR 147.130, all issuers of risk adjustment covered plans are required to cover PrEP and its ancillary services at zero cost sharing, consistent with the applicable USPSTF recommendation. Thus, we anticipated that the expected similarity across issuers' PrEP-associated cost sharing parameters would also mitigate the risk of adverse selection.

More recently, we have continued to analyze PrEP and its usage in the individual, small group, and merged markets as additional benefit years of enrollee-level EDGE data became

available. Because of PrEP's high costs relative to other preventive services, and in contrast to our initial assumptions about pricing decreases, our analysis of 2022 benefit year enrollee-level data⁵¹ found that PrEP services can pose a unique risk of adverse selection to the extent that utilization of PrEP services differs between plans. More specifically, our analysis found that there are statistically significant, substantial differences in PrEP prevalence between issuers in rating areas where PrEP use is most common, indicating that the addition of a PrEP factor in the adult and child risk adjustment models would be appropriate and would have a meaningful impact on risk adjustment State transfers. Furthermore, our analysis also found that other considerations that helped inform the current approach (such as the expected decrease in costs as generics entered the market and gained market share) have not addressed the uniquely high costs of PrEP as a preventive service as we previously expected. For these reasons, we started to reconsider our approach and whether it should evolve to address other costs in the market (such as PrEP) that could impact the assessment of actuarial risk but which do not indicate the presence of a specific diagnosis.

We therefore tested incorporating a non-RXC and non-HCC model factor for PrEP in the HHS risk adjustment adult and child models to capture differences in costs for PrEP utilizers relative to the average enrollee. To signify that the potential new factor would not indicate the presence of a specific active medical condition, we refer to the potential new type of factor as an "affiliated cost factor" (ACF), thereby distinguishing this new type of potential factor from RXCs and HCCs.

Generally speaking, similar to our approach when determining the HCCs and RXCs to be included in the HHS risk adjustment models,⁵² if adopted, we would rely on a set of principles to guide our decision making in developing any new ACF variable.

Principle 1—Like HCCs and RXCs, an ACF should be clinically meaningful, but in the case of ACFs, such variables

issued an order to stay proceedings in the District Court through the conclusion of proceedings in the United States Supreme Court. The Departments filed a petition for writ of certiorari on September 19, 2024. *Braidwood Mgmt., Inc. v. Becerra*, Civil Action No. 23–10326 (5th Cir. June 21, 2024), *petition for cert filed*, U.S. Sept. 19, 2024 (24–316).

⁴⁷ For example, colonoscopies typically require a combination of several services between the drugs needed for the colonoscopy and the professional and institutional claims for the visit and procedure itself. Likewise, contraception coverage often requires a doctor's visit to obtain a prescription for the contraception.

⁴⁸ See 86 FR 24164.

⁴⁹ See the 2018 Payment Notice (81 FR 94074 through 94080). See also the March 31, 2016, *HHS-Operated Risk Adjustment Methodology Meeting Questions & Answers*. June 8, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf>.

⁵⁰ See CMS. (2021). *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes*. Section 1.2.1 (Principles of Risk Adjustment). <https://www.cms.gov/files/document/2021-ra-technical-paper.pdf>.

⁵¹ Prior to the 2021 Benefit Year, Plan ID and Rating Area were not included as part of the enrollee-level data extracted from issuers' EDGE data submissions. As finalized in the 2023 Payment Notice (87 FR 27241 through 27251), we now extract these fields as part of the enrollee-level EDGE dataset and are able to include them in our analyses. As such, this analysis and proposal reflects our earliest opportunity to reliably detect differences in prevalence within rating areas for any medical expenditures, including PrEP.

⁵² See the 2014 Payment Notice Proposed Rule (77 FR 73128). See, also, the 2018 Payment Notice Proposed Rule (81 FR 61470).

would be comprised of National Drug Codes (NDCs) or procedure codes that are not indicative of a diagnosis for a specific serious medical condition, in contrast to HCCs and RXCs. In other words, an ACF may refer to a preventive service (as in the case of a potential PrEP ACF), or to classes of treatments that may be applicable to a wide variety of disease states and are therefore too general to indicate a specific diagnosis. Nevertheless, codes included in an ACF should all relate to a reasonably well-specified pharmacologic, therapeutic or chemical characteristic that defines the category. The adherence to the principle of clinical meaningfulness maintains the face validity of the classification system and the models' interpretability.

Principle 2—Like HCCs and RXCs, ACFs should meaningfully predict total medical and drug expenditures. Additionally, NDCs and procedure codes in an ACF should be reasonably homogeneous for their effect on current year costs, that is, the annual costs associated with NDCs or procedure codes triggering the ACF should fall within a reasonably limited range. Relative to the majority of NDCs or procedure codes in a given ACF, there should not be any extremely low or high cost NDCs or procedure codes included in the ACF.

Principle 3—Like HCCs and RXCs, because ACFs would affect State transfers, these factors should have adequate sample sizes to permit accurate and stable estimates of expenditures. For example, it is difficult to reliably determine the expected cost of extremely rare categories.⁵³

Principle 4—Like HCCs and RXCs, in creating an individual's clinical profile, hierarchies should be used to characterize the person's illness level within each disease process, where appropriate, while the effects of unrelated disease processes accumulate. Therefore, related HCCs, RXCs and ACFs should be treated hierarchically such that the most severe manifestation of a given specific potential disease process principally defines its impact on costs. As such, the presence of a relevant HCC or RXC in an enrollee's medical record, which would indicate the presence of a specific active medical

condition, should preclude the application of a related ACF because ACFs do not indicate the presence of a specific active medical condition.

Principle 5—As with HCCs and RXCs, issuers should not be penalized for a provider prescribing additional NDCs or coding additional medical conditions (monotonicity). This principle has two consequences for modeling of ACFs: (1) Like HCCs and RXCs, ACFs should not carry a negative payment weight; and (2) an HCC or RXC, or a relevant combination of an HCC, RXC, and interaction factor(s), reflecting the presence of a potential disease process to which the ACF is directly related should have at least as large a payment weight as the ACF.

Principle 6—Like RXCs, we expect ACFs to primarily be composed of NDCs or service codes. As such, the classification for ACFs, like RXCs, should assign NDCs or service codes to only one ACF or RXC variable (mutually exclusive classification). Because each NDC can map to more than one RXC or ACF, the classification should map NDCs to the primary RXC or ACF variable based on considerations such as route of administration, intended application of the product, ingredient list identifier, label, dosage form, and strength of the drug.

Principle 7—As with HCCs and RXCs, in evaluating the inclusion of ACFs, discretionary and noncredible drug or diagnosis categories should be excluded from payment models. ACFs that are particularly subject to prescribing variation or inappropriate prescribing by health plans or providers or to intentional or unintentional discretionary coding, or that are not clinically or empirically credible as cost predictors, should not be included.

In developing an ACF variable reflecting PrEP, we are considering whether PrEP satisfies these principles and what approaches are necessary to appropriately balance all seven principles. A PrEP ACF would easily satisfy Principle 1 (clinically meaningful and specific), Principle 2 (meaningful and predictable costs⁵⁴), Principle 3 (sample size), and Principle 7 (low risk of inappropriate prescribing). PrEP is a well-defined regimen of medication that is only recommended to enrollees who meet certain risk factors,⁵⁵ providing clinical

meaningfulness and specificity. Regarding cost, with the exception of generics,⁵⁶ the commonly available forms of PrEP are expensive and have similar costs,⁵⁷ making the costs both meaningful and predictable. Furthermore, there are a sufficient number of enrollees in the enrollee-level EDGE data to produce a reliable estimate of PrEP costs for the HHS risk adjustment adult and child models. Finally, for a preventive service such as PrEP, we consider the uniquely high costs and low likelihood of overprescribing to provide clinical and empirical credibility towards cost prediction, thereby satisfying the low risk of inappropriate prescribing required by Principle 7. Specifically, we consider there to be a low likelihood of overprescribing PrEP due to the high degree of ancillary services generally required to obtain and maintain access to a PrEP prescription. For example, as reflected by the U.S. Public Health Service clinical practice guidelines for PrEP,⁵⁸ patients receiving oral PrEP generally must see a provider to be tested for HIV and other sexually transmitted infections every 3 months and have key liver and kidney function indicators tested every 6 months to 1 year.⁵⁹ Additionally, we suspect⁶⁰ that

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>

⁵⁶ See, *supra*, note 54.

⁵⁷ See NADAC (National Average Drug Acquisition Cost) 2024 reference data (available at <https://data.medicaid.gov/dataset/99315a95-37ac-4eee-946a-3c523b4c481e>) and the NADAC Equivalency Metrics (available at <https://www.medicaid.gov/medicaid/prescription-drugs/downloads/retail-price-survey/nadac-equiv-metrics.pdf>). See also <https://getprepbroward.com/documents/Long-Acting-Injectable-PrEP.pdf> for estimates of the cost of Long Acting Injectable PrEP, which is administered by a provider in a clinical setting and is not available in NADAC data.

⁵⁸ See, *supra*, note 55.

⁵⁹ The costs of these ancillary services are currently captured in the age-sex coefficients, but the addition of a PrEP ACF to the HHS risk adjustment adult and child models would shift the risk contributed by ancillary services out of the age-sex factors into the PrEP ACF factor.

⁶⁰ In the enrollee-level EDGE data, we are unable to assess utilization rates from PrEP indicated populations because we are generally unable to identify the population of enrollees who would be eligible for PrEP but who are not utilizing the preventive service. Additionally, specific estimates of PrEP utilization among specific indicated populations are difficult to attain from other data sources at this point in time. The CDC has paused the publication of estimates of PrEP coverage in indicated populations and has advised against citing specific data points until June 2025 due to data availability issues. (See Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 territories and freely associated States, 2022. *HIV Surveillance Supplemental Report* 2024; 29(No. 2). <https://www.cdc.gov/hiv-data/nhss/national-hiv-prevention-and-care-outcomes.html>).

⁵³ For example, one extremely rare category that we have continued to analyze and consider for incorporation in the HHS risk adjustment models is gene therapy treatments. However, because these treatments are for rare conditions, and because there is substantial variation in costs from patient to patient for these treatments, through our ongoing monitoring and consideration of gene therapy treatments, we continue to find insufficient sample size and stable estimates of costs for the purposes of creating a new factor for these treatments in the HHS risk adjustment models.

⁵⁴ As discussed later in this section, it may be appropriate to remove generic drugs to ensure homogeneity of costs within a PrEP ACF.

⁵⁵ See Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline.

there is a relatively low utilization rate of PrEP services among specific indicated populations, which would also indicate a low likelihood that PrEP is being overprescribed.

As mentioned above, we have found that PrEP overall satisfies Principle 2, having meaningful and predictable costs. In particular, our analyses found that the utilization patterns of PrEP medications have been fairly consistent year-over-year, with previously approved versions of PrEP medications maintaining substantial market share despite the availability of generic versions and new market entrants such as Apretude. If ACF medications and services that were commonly used in 1 year were largely supplanted by different medications or services in the following year, the cost predictions based on previous years of data may be inaccurate. Nevertheless, although we will continue to monitor the market for PrEP drugs, we generally do not anticipate substantial decrease in costs in the near future for enrollees taking brand name drugs due to the more convenient drugs and dose-forms (for example, long-acting injectable forms) coming to market⁶¹ and the retention of market share by existing branded drugs.

Despite the overall anticipation that PrEP costs are consistent and will remain high over the next several years, we have found that there exists a large disparity in the costs of generic PrEP medication and the costs of brand name PrEP medication.⁶² Due to this disparity, if we include all PrEP medications in the definition of an ACF, the estimated coefficient will likely lead to overprediction for enrollees receiving generic medications and underprediction for enrollees receiving brand name medications. As such, it may be appropriate to exclude generic PrEP medication from the PrEP ACF, if one is adopted, which would exclude about 50 percent of enrollees with a PrEP prescription claim from the calculation of a PrEP ACF coefficient according to 2022 enrollee-level EDGE data. Such a low-cost exclusion from the ACF may improve predictions for enrollees receiving either generic or brand name PrEP medication and has precedent in our adoption of other factors in the HHS risk adjustment models. Specifically, we previously excluded generic drugs from RXC 9,

Immune Suppressants and Immunomodulators, due to concern over patient access and health plan selection behavior.⁶³ However, we believe that such an exclusion for a potential PrEP ACF could create incentives for prescribing brand over generic PrEP and therefore we solicit comments on balancing these considerations to help inform our consideration of the design of a potential PrEP ACF variable.

As outlined by our discussion of Principles 1, 2, 3, and 7, our preliminary testing found minimal empirical concerns with a new PrEP ACF variable being added to the current HHS risk adjustment adult and child models, as the sample size for such a variable is reasonable for both the adult and child models, the clinical specifications are well defined, costs are generally predictable, and the resulting preliminary coefficient estimates for PrEP in the adult and child models are meaningful. However, in assessing Principles 4 (hierarchical factor definitions), 5 (monotonicity), and 6 (mutually exclusive classification), we found that the creation of a PrEP ACF variable would require further careful consideration.

To satisfy Principle 4 (hierarchical factor definitions), the most severe manifestation of a given specific potential disease process must principally define its impact on costs. Therefore, related HCCs and RXCs (in the case of a PrEP ACF, the related HCC 1 for HIV/AIDS, and RXC 1 for anti-HIV agents) should be treated hierarchically. As such, in considering PrEP as a potential ACF, the presence of HCC 1 or RXC 1 in an enrollee's medical record should preclude the application of the PrEP ACF, as the prevention of HIV infection clearly indicates a less severe manifestation of the specific potential disease process than treatment of an active HIV infection.

However, the coefficient for HIV/AIDS (HCC 1) in the adult models⁶⁴ has generally been lower than the coefficient we estimate would be calculated for a PrEP ACF. As such, without constraints applied to the HCC 1, RXC 1, and PrEP ACF coefficients, an adult enrollee who was on PrEP and later tested positive for HIV but did not

start anti-retroviral therapy for treatment within the same benefit year would have their risk score decrease between the initial application of the PrEP ACF, and its later replacement with HCC 1, violating monotonicity (Principle 5). Such enrollees make up a very small proportion of enrollees with a PrEP prescription claim (approximately 1.9 percent of enrollees with a PrEP prescription claim in the 2021 enrollee-level EDGE data). Additionally, this violation of monotonicity is not expected to take place in the HHS risk adjustment child models, as the lack of RXCs in the child models causes the coefficient for HCC 1 to be high enough that a PrEP ACF coefficient would not exceed the HCC for HIV/AIDS among child enrollees. Nevertheless, for consistency with the established principles for the HHS-operated risk adjustment program and the proposed principles to guide development of potential new ACF variables, we are considering solutions, described below, to the monotonicity concern for a PrEP ACF in the HHS risk adjustment adult models should we finalize the adoption of the proposed factor.

Additionally, a PrEP ACF could pose issues for mutually exclusive classification (Principle 6). Specifically, the compounds used in PrEP medication are also used to treat HIV. As such, NDCs for medications used for PrEP or the individual compounds alone are not enough to distinguish between an enrollee receiving PrEP and an enrollee in treatment for an active HIV infection. However, due to the necessity of the additional anti-retroviral compounds for HIV infection treatment, with special considerations and data filtering, we are generally able to distinguish enrollees that are receiving antiretroviral therapy for PrEP and those receiving antiretroviral treatment as treatment for HIV/AIDS for the purposes of calculating plan liability with 100 percent cost sharing for PrEP and typical cost sharing treatment of HIV infection.⁶⁵ ⁶⁶ To address the

⁶⁵ See the 2021 Payment Notice (85 FR 29187).

⁶⁶ The medications used to treat HIV are also used as post-exposure prophylaxis (PEP). Unlike PrEP, we are unable to distinguish between prescriptions for HIV treatment and prescriptions for PEP because the current guidelines for known exposures to HIV recommend the prescription of the same drugs as are used in treatment (See for example, <https://stacks.cdc.gov/view/cdc/20711>) <https://stacks.cdc.gov/view/cdc/20711>). However, we note that PEP requires a 28-day treatment regimen and, as such, has a much more limited impact on calculations of plan liability and risk than either treatment for an active HIV infection or PrEP. (See, for example, <https://hivinfo.nih.gov/understanding-hiv/fact-sheets/post-exposure-prophylaxis-pep#:~:text=PEP%20stands%20for%20post%20exposure,used%20only%20in%20emergency%20situations.>)

⁶¹ Long-acting injectable PrEP may be beneficial in encouraging adherence to a PrEP medication regimen. (See, for example, <https://getprepbroward.com/documents/Long-Acting-Injectable-PrEP.pdf>). As such, we anticipate that treatment guidelines may recommend its use over oral PrEP in the future.

⁶² See, supra, note 57.

⁶³ See, for example, the 2019 Payment Notice (83 FR 16942).

⁶⁴ Risk associated with HIV infection can be expressed in the value of HCC 1 or in the value of RXC 1. Because these factors are highly correlated, the value of each coefficient taken alone may fluctuate between benefit years. However, the additive value of these two factors in the HHS risk adjustment adult models is fairly consistent year-over-year.

concerns for adherence to Principle 6, we will need to create a mutually exclusive NDC classification between RXC 1 and a PrEP ACF.

To address the HHS risk adjustment adult modeling concerns we identified regarding Principles 4, 5 and 6, we are considering two alternative approaches. First, we could modify the current definition of RXC 1 (Anti-HIV agents) by treating PrEP NDCs as RXC 1 NDCs in limited circumstances based on individual enrollee characteristics. Alternatively, we could place the PrEP ACF in a hierarchy with RXC 1 but define no hierarchical restrictions between PrEP and HCC 1 (HIV/AIDS). We discuss these alternatives in detail below.

Under the first approach, modifying the current definition of RXC 1, we would add PrEP NDCs into RXC 1 (Anti-HIV agents) in limited circumstances to address situations where the adult enrollee has both a claim for PrEP and a claim for RXC 1 within the benefit year. Operationally, to capture these cases, the adult enrollees with a PrEP prescription claim would receive the RXC 1 flag instead of the ACF only in cases where the enrollee has both a PrEP prescription claim and an HIV diagnosis but does not have a typical RXC 1 prescription claim because the enrollee did not begin treatment for HIV, or because their treatment medication was provided at no cost to the issuer and therefore no claim was submitted to EDGE. As such, a PrEP NDC's classification as RXC 1 or the ACF would be contingent on the presence of HCC 1 (HIV/AIDS) on an adult enrollee's record. We estimate that less than 2 percent of adult enrollees with a PrEP prescription claim would meet these criteria, and that such enrollees would account for less than 1 percent of enrollees receiving RXC 1. As such, the sample size of the PrEP ACF would remain high and the impact on the RXC 1 coefficient would be minimal. This approach to defining the hierarchical

relationship between HCC 1, RXC 1, and the PrEP ACF would ensure that an adult enrollee with a PrEP prescription claim who later tested positive for HIV would have an increase in their risk score as a result of the additional diagnosis, satisfying Principles 4 (hierarchical factor definitions) and 5 (monotonicity). Although this approach would not be strictly consistent with mutually exclusive classification of diagnosis codes and NDCs into only one variable (Principle 6), we find this to be acceptable in this limited circumstance because it would precisely dictate which model factor an adult enrollee would receive (which satisfies the intent of Principle 6, mutually exclusive classification) and because PrEP medications can be part of an approved HIV treatment protocol when additional anti-retroviral drugs are used. Thus, it is not unreasonable to assume that the few adult enrollees with PrEP prescription claims and an HIV diagnosis are also receiving the additional medications needed to meet treatment requirements.⁶⁷

Under the alternative approach, we would address the violation of monotonicity in the HHS risk adjustment adult models by placing the PrEP ACF below RXC 1 in a hierarchy but defining no hierarchical relationship between the PrEP ACF and HCC 1 (HIV/AIDS), allowing adult enrollees without RXC 1 to receive the PrEP ACF along with HCC 1 in cases where the enrollee has both a PrEP prescription claim and an HCC 1 diagnosis in their medical records for the benefit year. This approach would also ensure that an adult enrollee with a PrEP prescription claim who later tested positive for HIV would have an increase in their risk score as a result of the additional diagnosis, satisfying Principles 4

(hierarchical factor definitions) and 5 (monotonicity). This alternative PrEP ACF–RXC 1 hierarchy approach would likewise satisfy the intent of Principle 6 (mutually exclusive classification) by using similar considerations and filtering steps to those we currently use in our simulation of plan liability for PrEP. We solicit comments on addressing these hierarchy, monotonicity, and mutual exclusivity concerns, and both alternative approaches outlined above that are designed to address those concerns.

Table 2 below displays our testing of estimated values for the proposed PrEP ACF for the 2026 benefit year adult models using only 2021 benefit year enrollee-level EDGE data, but otherwise following the specifications of the 2025 benefit year HHS risk adjustment adult models.⁶⁸ We also included the values of the adult model factors that would likely be most impacted by the addition of a PrEP ACF to the 2026 benefit year risk adjustment models in table 2. This helps demonstrate whether the PrEP ACF would adhere to Principles 4, 5, and 6 described above. As indicated in the table, the addition of the adult model coefficients for a PrEP ACF (in each metal level) to the adult models would only minorly impact other coefficients, with the most impacted model coefficients being the age-sex coefficients for males between the ages of 25 and 44, RXC 1 (Anti-HIV Agents), and a small handful of other HCCs and RXCs. All impacts beyond those displayed in this table reflect absolute impacts on HHS risk adjustment adult model coefficient values of less than 0.01. However, we note that these values have not been subjected to either our normal modeling constraints, nor any of the constraints discussed in relation to Principles 4, 5 and 6.

⁶⁷ It is possible such medications may not appear in the enrollee-level EDGE data if the issuer cost is completely covered by rebates or other assistance. In such cases, the cost of the medication would not influence plan liability calculations and would not impact the coefficient of a PrEP ACF.

⁶⁸ For the specifications of the 2025 benefit year HHS risk adjustment adult and child models, including the Hepatitis C pricing adjustment and the list of factors included in the models, see the 2025 Payment Notice (89 FR 26238 through 26256).

TABLE 2: Estimated Unconstrained HHS Risk Adjustment Adult Model Factors for a PrEP ACF (ACF 01) and Other Adult Model Factors with Absolute Coefficient Impacts of at Least .01 When Adding a PrEP ACF to the Adult Models Using the 2021 Enrollee-Level EDGE Data

Metal Level	HCC/RXC/ACF Number	Factor	Estimated Model Coefficient	Estimated Coefficient Change Relative to Model Without PrEP ACF*
Platinum	ACF 01	HIV Pre-Exposure Prophylaxis	2.678	+2.678
		Age 25-29, Male	0.203	-0.017
		Age 30-34, Male	0.236	-0.019
		Age 35-39, Male	0.256	-0.016
		Age 40-44, Male	0.290	-0.012
	HCC003	Central Nervous System Infections, Except Viral Meningitis	7.525	-0.014
	HCC004	Viral or Unspecified Meningitis	7.607	-0.013
	HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.551	-0.010
	HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	0.861	-0.010
	HCC090	Personality Disorders	0.685	-0.010
	RXC 01	Anti-HIV Agents	4.550	+0.010
	RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.757	-0.039
	RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.827	+0.040
	RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	37.424	+0.015
Gold	ACF 01	HIV Pre-Exposure Prophylaxis	2.618	+2.618
		Age 25-29, Male	0.135	-0.016
		Age 30-34, Male	0.163	-0.018
		Age 35-39, Male	0.180	-0.015
		Age 40-44, Male	0.209	-0.011
	HCC003	Central Nervous System Infections, Except Viral Meningitis	7.438	-0.014
	HCC004	Viral or Unspecified Meningitis	7.512	-0.013

Metal Level	HCC/RXC/ACF		Estimated Model Coefficient	Estimated Coefficient Change Relative to Model Without PrEP ACF*
	Number	Factor		
	HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.492	-0.010
	HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	0.772	-0.010
	IICC090	Personality Disorders	0.608	-0.011
	RXC 01	Anti-HIV Agents	4.092	+0.010
	RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.235	-0.039
	RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.692	+0.039
	RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	37.489	+0.014
Silver	ACF 01	HIV Pre-Exposure Prophylaxis	2.553	+2.553
		Age 25-29, Male	0.089	-0.016
		Age 30-34, Male	0.111	-0.018
		Age 35-39, Male	0.123	-0.015
		Age 40-44, Male	0.147	-0.012
	IICC003	Central Nervous System Infections, Except Viral Meningitis	7.398	-0.013
	IICC004	Viral or Unspecified Meningitis	7.464	-0.013
	HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	0.691	-0.010
	HCC090	Personality Disorders	0.514	-0.011
	RXC 01	Anti-HIV Agents	3.798	+0.010
	RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.190	-0.037
	RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.598	+0.038
	RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	37.573	+0.014
Bronze	ACF 01	HIV Pre-Exposure Prophylaxis	2.495	+2.495
		Age 25-29, Male	0.057	-0.015
		Age 30-34, Male	0.073	-0.018
		Age 35-39, Male	0.081	-0.014
		Age 40-44, Male	0.100	-0.011
	HCC003	Central Nervous System Infections, Except Viral Meningitis	7.331	-0.013

Metal Level	HCC/RXC/ACF Number	Factor	Estimated Model Coefficient	Estimated Coefficient Change Relative to Model Without PrEP
				ACF*
	HCC004	Viral or Unspecified Meningitis	7.380	-0.012
	HCC090	Personality Disorders	0.395	-0.010
	RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.023	-0.036
	RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.472	+0.038
	RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	37.680	+0.014
Catastrophic	ACF 01	HIV Pre-Exposure Prophylaxis	2.493	+2.493
		Age 25-29, Male	0.056	-0.015
		Age 30-34, Male	0.072	-0.018
		Age 35-39, Male	0.079	-0.015
		Age 40-44, Male	0.099	-0.011
	HCC003	Central Nervous System Infections, Except Viral Meningitis	7.329	-0.013
	HCC004	Viral or Unspecified Meningitis	7.377	-0.013
	HCC090	Personality Disorders	0.391	-0.010
	RXC 01	Anti-HIV Agents	3.343	+0.010
	RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.022	-0.036
	RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.468	+0.038
	RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	37.687	+0.013

*For these estimates, for consistency with the estimated model coefficients, which were calculated using the 2021 enrollee-level EDGE data and 2025 benefit year risk adjustment model specifications, we estimated these coefficient changes by comparing the estimated model coefficients to the final 2025 benefit year HHS risk adjustment model coefficients for each metal level.

Table 3 below displays estimated values for the proposed PrEP ACF for the 2026 benefit year HHS risk adjustment child models using only 2021 benefit year enrollee-level EDGE data, but otherwise following the

specifications of the 2025 benefit year HHS risk adjustment child models.⁶⁹ Unlike the adult models, for the HHS risk adjustment child models, our

⁶⁹ Ibid.

testing found there are no impacts greater than 0.01 to the unconstrained coefficients for other child model factors. In this analysis for the child models, the approximate value of the

PrEP ACF coefficient for children for the 2026 benefit year would fall below the HCC 1 (HIV/AIDS) coefficient for each

metal level,⁷⁰ affirming that the identified concerns over Principles 4, 5 and 6 among the HHS risk adjustment

adult models do not apply to the HHS risk adjustment child models.

TABLE 3: Estimated Unconstrained HHS Risk Adjustment Child Model Factors for a PrEP ACF (ACF 01)

Estimated Model Coefficient for	
Metal Level	ACF 01
Platinum	1.304
Gold	1.263
Silver	1.214
Bronze	1.161
Catastrophic	1.160

Again, the above coefficient values in tables 2 and 3 have been calculated using the 2021 enrollee-level EDGE data only, with the 2025 benefit year HHS risk adjustment model specifications, and without our normal modeling constraints nor any of the constraints discussed in relation to Principles 4, 5 and 6. Although we anticipate that these values will change slightly when the modeling constraints and the 2026 benefit year risk adjustment model specifications are applied, if the proposed new PrEP ACF variable is added to the adult and child models, we believe these offer reliable estimates of the potential impact of the adoption of the proposed new PrEP ACF variable on other factors and approximate values for the proposed draft new PrEP ACF coefficients for the adult and child models. If this proposal is finalized, the final coefficients will be made available in the final rule or through subsequent notice-and-comment rulemaking or guidance, as appropriate.

We solicit comments on our proposal to create a new ACF category of model factors for incorporation into the HHS risk adjustment models to account for unique medical expenses or services (such as PrEP) that do not meet the criteria to qualify as HCC or RXC factors, but impact the actuarial risk presented to issuers of risk adjustment covered plans. In addition, we solicit

comments on our proposal to modify the treatment of PrEP in the HHS risk adjustment adult and child models beginning with the 2026 benefit year, as well as how to methodologically define a potential ACF category of model factors that accounts for PrEP (or other unique medical expenses or services) and what other considerations should be part of the analysis and modeling for this proposed new category of model factors (such as the availability of drug rebates⁷¹ or differences in medication adherence for PrEP). Furthermore, we solicit comments regarding the principles to guide inclusion of potential ACF factors and the discussed alternative approaches for defining a PrEP ACF's hierarchical relationship to HCC 1 and RXC1 to address the concerns related to hierarchical factor definitions (Principle 4), violations of monotonicity (Principle 5), and violations of mutually exclusive classification (Principle 6) in the HHS risk adjustment adult models. Additionally, we solicit comments on whether generic versions of PrEP medication should be excluded from the definition of the proposed ACF for PrEP. Lastly, we solicit comments concerning whether there are any similar medical expenses or services that we should consider for potential new ACFs alongside PrEP.

d. Proposed List of Factors To Be Employed in the HHS Risk Adjustment Models (\$ 153.320)

The proposed 2026 benefit year HHS risk adjustment model factors resulting from the equally weighted (averaged) blended factors from separately solved models using the 2020, 2021, and 2022 enrollee-level EDGE data are shown in tables 4 through 9.⁷² The HHS risk adjustment adult, child, and infant models have been truncated to account for the high-cost risk pool payment parameters by removing 60 percent of costs above the \$1 million threshold.⁷³ Table 4 contains proposed factors for each adult model, including the age-sex, HCCs, RXCs, RXC-HCC interactions, interacted HCC counts, and enrollment duration coefficients. Table 5 contains the proposed factors for each child model, including the age-sex, HCCs, and interacted HCC counts coefficients.⁷⁴ Table 6 lists the proposed HCCs selected for the interacted HCC counts factors that would apply to the HHS risk adjustment adult and child models. Table 7 contains the proposed factors for each HHS risk adjustment infant model. Tables 8 and 9 contain the HCCs included in the HHS risk adjustment infant models' maturity and severity categories, respectively.

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⁷⁰ As compared to the HCC 1 coefficients in table 5.

⁷¹ For example, we believe there are likely substantial rebates for Descovy that are not captured in issuers' EDGE data submissions. See, for example, Dickson, S., Gabriel, N., and Hernandez, I. Estimated changes in price discounts for tenofovir-inclusive HIV treatments following introduction of tenofovir alafenamide. *AIDS*. 2022 Dec 1;36(15):2225–2227. doi: 10.1097/QAD.0000000000003401. See, also, Krakower, D.

and Marcus, J.L. Commercial Determinants of Access to HIV Preexposure Prophylaxis. *JAMA Network Open*. 2023;6(11):e2342759. doi:10.1001/jamanetworkopen.2023.42759. See, also, McManus, K.A., et al. Geographic Variation in Qualified Health Plan Coverage and Prior Authorization Requirements for HIV Preexposure Prophylaxis. *JAMA Network Open*. 2023;6(11):e2342781. doi:10.1001/jamanetworkopen.2023.42781.

⁷² See, supra, note 36.

⁷³ As finalized in the 2020 Payment Notice (84 FR 17466 through 17468), we will maintain the high-cost risk pool parameters for the 2020 benefit year and beyond, unless amended through notice-and-comment rulemaking. We are not proposing changes to the high-cost risk pool parameters for the 2026 benefit year. Therefore, we will maintain the \$1 million threshold and 60 percent coinsurance rate for the 2026 benefit year.

⁷⁴ See, supra, note 36.

TABLE 4: Proposed Adult HHS Risk Adjustment Model Factors for the 2026 Benefit Year

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors						
	Age 21-24, Male	0.196	0.136	0.096	0.068	0.063
	Age 25-29, Male	0.208	0.144	0.100	0.070	0.064
	Age 30-34, Male	0.240	0.171	0.122	0.086	0.079
	Age 35-39, Male	0.258	0.185	0.131	0.091	0.083
	Age 40-44, Male	0.288	0.210	0.152	0.107	0.098
	Age 45-49, Male	0.322	0.241	0.179	0.131	0.122
	Age 50-54, Male	0.381	0.293	0.225	0.171	0.160
	Age 55-59, Male	0.423	0.328	0.255	0.196	0.185
	Age 60-64, Male	0.466	0.363	0.283	0.217	0.204
	Age 21-24, Female	0.285	0.199	0.131	0.083	0.073
	Age 25-29, Female	0.312	0.218	0.144	0.090	0.078
	Age 30-34, Female	0.377	0.278	0.199	0.139	0.126
	Age 35-39, Female	0.428	0.326	0.245	0.181	0.169
	Age 40-44, Female	0.478	0.372	0.287	0.217	0.203
	Age 45-49, Female	0.483	0.375	0.287	0.213	0.199
	Age 50-54, Female	0.508	0.397	0.305	0.228	0.212
	Age 55-59, Female	0.469	0.359	0.267	0.192	0.176
	Age 60-64, Female	0.459	0.347	0.253	0.177	0.161
Diagnosis Factors						
HCC001	HIV/AIDS	0.324	0.249	0.214	0.184	0.182
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	8.769	8.567	8.520	8.428	8.425
HCC003	Central Nervous System Infections, Except Viral Meningitis	7.904	7.806	7.760	7.687	7.675
HCC004	Viral or Unspecified Meningitis	7.686	7.583	7.533	7.454	7.442
HCC006	Opportunistic Infections	8.506	8.456	8.403	8.327	8.309
HCC008	Metastatic Cancer	22.556	22.165	22.139	22.021	22.026
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	12.532	12.260	12.214	12.096	12.090
HCC010	Non-Hodgkin Lymphomas and Other Cancers and Tumors	5.519	5.346	5.280	5.167	5.154
HCC011	Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.718	3.537	3.464	3.342	3.327
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	2.399	2.267	2.201	2.101	2.087
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	0.972	0.882	0.795	0.690	0.671
HCC018	Pancreas Transplant Status	6.001	6.000	6.012	6.016	6.008
HCC019	Diabetes with Acute Complications	0.224	0.182	0.141	0.101	0.093
HCC020	Diabetes with Chronic Complications	0.224	0.182	0.141	0.101	0.093
HCC021	Diabetes without Complication	0.224	0.182	0.141	0.101	0.093
HCC022	Type 1 Diabetes Mellitus, add-on to Diabetes HCCs 19-21	0.224	0.200	0.163	0.098	0.083
HCC023	Protein-Calorie Malnutrition	10.678	10.559	10.519	10.449	10.441
HCC026	Mucopolysaccharidosis	21.504	21.326	21.298	21.232	21.231
HCC027	Lipidoses and Glycogenosis	21.504	21.326	21.298	21.232	21.231
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders	6.053	5.953	5.914	5.848	5.839

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders	1.277	1.204	1.153	1.080	1.067
HCC034	Liver Transplant Status/Complications	5.771	5.833	5.891	5.973	5.986
HCC035_1 ^a	Acute Liver Failure/Disease, Including Neonatal Hepatitis	7.001	6.815	6.775	6.699	6.700
HCC035_2	Chronic Liver Failure/End-Stage Liver Disorders	2.215	2.052	2.012	1.928	1.922
HCC036	Cirrhosis of Liver	0.668	0.588	0.546	0.478	0.467
HCC037_1	Chronic Viral Hepatitis C	0.540	0.480	0.432	0.378	0.371
HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.540	0.480	0.432	0.378	0.371
HCC041	Intestine Transplant Status/Complications	5.771	5.833	5.891	5.973	5.986
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	10.677	10.534	10.530	10.490	10.492
HCC045	Intestinal Obstruction	4.906	4.701	4.639	4.517	4.506
HCC046	Chronic Pancreatitis	2.255	2.087	2.037	1.945	1.939
HCC047	Acute Pancreatitis	2.255	2.087	2.032	1.922	1.913
HCC048	Inflammatory Bowel Disease	1.988	1.892	1.814	1.689	1.663
HCC054	Necrotizing Fasciitis	7.354	7.204	7.177	7.119	7.116
HCC055	Bone/Joint/Muscle Infections/Necrosis	4.337	4.167	4.140	4.077	4.077
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders	1.220	1.126	1.067	0.987	0.974
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.361	0.295	0.220	0.124	0.104
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies	1.743	1.623	1.560	1.460	1.446
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders	1.743	1.623	1.560	1.460	1.446
HCC063	Cleft Lip/Cleft Palate	0.716	0.616	0.552	0.467	0.454
HCC066	Hemophilia	73.949	73.659	73.629	73.537	73.541
HCC067	Mycelodysplastic Syndromes and Myelofibrosis	10.804	10.680	10.652	10.586	10.578
HCC068	Aplastic Anemia	10.804	10.680	10.652	10.586	10.578
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	10.804	10.680	10.652	10.586	10.578
HCC070	Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero	1.693	1.605	1.548	1.476	1.465
HCC071	Sickle-Cell Disorders, Except Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major	1.653	1.584	1.538	1.476	1.465
HCC073	Combined and Other Severe Immunodeficiencies	4.305	4.215	4.189	4.135	4.128
HCC074	Disorders of the Immune Mechanism	4.305	4.215	4.189	4.135	4.128
HCC075	Coagulation Defects and Other Specified Hematological Disorders	2.134	2.053	2.005	1.934	1.922
HCC081	Drug Use with Psychotic Complications	1.503	1.376	1.284	1.151	1.126
HCC082	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	1.503	1.376	1.284	1.151	1.126
HCC083	Alcohol Use with Psychotic Complications	0.863	0.751	0.678	0.575	0.558
HCC084	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	0.863	0.751	0.678	0.575	0.558

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC087_1	Schizophrenia	2.220	2.055	1.974	1.849	1.834
HCC087_2	Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	2.107	1.948	1.863	1.725	1.705
HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	0.929	0.834	0.750	0.640	0.619
HCC090	Personality Disorders	0.643	0.569	0.479	0.372	0.348
HCC094	Anorexia/Bulimia Nervosa	1.901	1.797	1.730	1.627	1.610
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	9.086	9.059	9.029	8.993	8.981
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	0.819	0.758	0.713	0.655	0.644
HCC102	Autistic Disorder	0.684	0.610	0.524	0.431	0.411
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder	0.643	0.569	0.479	0.372	0.348
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	9.269	9.111	9.058	8.961	8.951
HCC107	Quadriplegia	9.269	9.111	9.058	8.961	8.951
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	6.184	6.041	5.985	5.886	5.874
HCC109	Paraplegia	6.184	6.041	5.985	5.886	5.874
HCC110	Spinal Cord Disorders/Injuries	4.886	4.708	4.657	4.554	4.544
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	4.966	4.824	4.756	4.643	4.627
HCC112	Quadriplegic Cerebral Palsy	0.612	0.524	0.458	0.364	0.347
HCC113	Cerebral Palsy, Except Quadriplegic	0.339	0.274	0.220	0.148	0.134
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.165	1.083	1.027	0.938	0.921
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.056	4.973	4.956	4.917	4.915
HCC117	Muscular Dystrophy	1.328	1.239	1.173	1.079	1.062
HCC118	Multiple Sclerosis	2.666	2.536	2.479	2.383	2.370
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	1.328	1.239	1.173	1.079	1.062
HCC120	Seizure Disorders and Convulsions	0.940	0.850	0.787	0.696	0.681
HCC121	Hydrocephalus	9.454	9.362	9.314	9.244	9.232
HCC122	Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic Brain Compression/Anoxic Damage	9.882	9.748	9.694	9.603	9.590
HCC123	Narcolepsy and Cataplexy	4.531	4.404	4.343	4.247	4.233
HCC125	Respirator Dependence/Tracheostomy Status	21.608	21.401	21.360	21.273	21.271
HCC126	Respiratory Arrest	8.172	7.957	7.913	7.823	7.821
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	8.172	7.957	7.913	7.823	7.821
HCC128	Heart Assistive Device/Artificial Heart	15.142	15.048	15.018	14.981	14.985
HCC129	Heart Transplant Status/Complications	15.142	15.048	15.018	14.981	14.985
HCC130	Heart Failure	1.769	1.684	1.647	1.582	1.572
HCC131	Acute Myocardial Infarction	4.648	4.428	4.402	4.328	4.331

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease	3.381	3.185	3.139	3.036	3.030
HCC135	Heart Infection/Inflammation, Except Rheumatic	8.377	8.292	8.237	8.153	8.137
HCC137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	2.031	1.943	1.886	1.810	1.798
HCC138	Major Congenital Heart/Circulatory Disorders	2.031	1.943	1.886	1.810	1.798
HCC139	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	2.031	1.943	1.886	1.810	1.798
HCC142	Specified Heart Arrhythmias	1.828	1.726	1.660	1.556	1.536
HCC145	Intracranial Hemorrhage	10.183	10.022	9.976	9.889	9.882
HCC146	Ischemic or Unspecified Stroke	1.382	1.269	1.232	1.160	1.153
HCC149	Cerebral Aneurysm and Arteriovenous Malformation	2.096	1.979	1.920	1.819	1.803
HCC150	Hemiplegia/Hemiparesis	2.952	2.831	2.813	2.765	2.766
HCC151	Monoplegia, Other Paralytic Syndromes	2.464	2.353	2.306	2.226	2.217
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene	7.862	7.701	7.708	7.682	7.691
HCC154	Vascular Disease with Complications	4.946	4.803	4.760	4.678	4.670
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	7.348	7.269	7.200	7.095	7.071
HCC158	Lung Transplant Status/Complications	11.134	11.054	11.027	10.996	11.000
HCC159	Cystic Fibrosis	3.817	3.697	3.645	3.565	3.555
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.620	0.546	0.472	0.381	0.363
HCC161_1	Severe Asthma	0.620	0.546	0.472	0.381	0.363
HCC161_2	Asthma, Except Severe	0.620	0.546	0.472	0.381	0.363
HCC162	Fibrosis of Lung and Other Lung Disorders	1.544	1.465	1.411	1.329	1.314
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	7.234	7.126	7.082	7.011	7.001
HCC174	Exudative Macular Degeneration	1.162	1.038	0.948	0.814	0.793
HCC183	Kidney Transplant Status/Complications	6.001	6.000	6.012	6.016	6.008
HCC184	End Stage Renal Disease	19.250	18.854	18.967	18.808	18.721
HCC187	Chronic Kidney Disease, Stage 5	0.723	0.649	0.643	0.605	0.594
HCC188	Chronic Kidney Disease, Severe (Stage 4)	0.723	0.649	0.643	0.605	0.594
HCC203	Ectopic and Molar Pregnancy	1.579	1.424	1.295	1.099	1.065
HCC204	Miscarriage with Complications	0.605	0.530	0.412	0.252	0.210
HCC205	Miscarriage with No or Minor Complications	0.605	0.530	0.412	0.252	0.210
HCC207	Pregnancy with Delivery with Major Complications	3.611	3.337	3.146	2.824	2.782
HCC208	Pregnancy with Delivery with Complications	3.611	3.337	3.146	2.824	2.782
HCC209	Pregnancy with Delivery with No or Minor Complications	2.666	2.465	2.249	1.883	1.811
HCC210	(Ongoing) Pregnancy without Delivery with Major Complications	0.695	0.606	0.465	0.292	0.252
HCC211	(Ongoing) Pregnancy without Delivery with Complications	0.464	0.395	0.270	0.138	0.107

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC212	(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.011	0.000	0.000	0.000	0.000
HCC217	Chronic Ulcer of Skin, Except Pressure	1.442	1.349	1.315	1.257	1.251
HCC218	Extensive Third-Degree Burns	25.026	24.830	24.788	24.706	24.701
HCC219	Major Skin Burn or Condition	2.495	2.374	2.316	2.230	2.220
HCC223	Severe Head Injury	17.509	17.362	17.298	17.192	17.176
HCC226	Hip and Pelvic Fractures	7.706	7.461	7.433	7.349	7.351
HCC228	Vertebral Fractures without Spinal Cord Injury	4.015	3.856	3.784	3.662	3.646
HCC234	Traumatic Amputations and Amputation Complications	4.454	4.299	4.273	4.209	4.208
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	18.843	18.873	18.850	18.846	18.843
HCC253	Artificial Openings for Feeding or Elimination	5.485	5.366	5.341	5.287	5.284
HCC254	Amputation Status, Upper Limb or Lower Limb	0.862	0.766	0.731	0.669	0.663
Interacted HCC Counts Factors						
	Severe illness, 1 payment HCC	-5.771	-5.833	-5.891	-5.973	-5.986
	Severe illness, 2 payment HCCs	-5.615	-5.693	-5.729	-5.792	-5.798
	Severe illness, 3 payment HCCs	-4.802	-4.863	-4.817	-4.790	-4.774
	Severe illness, 4 payment HCCs	-4.155	-4.159	-4.030	-3.889	-3.848
	Severe illness, 5 payment HCCs	-3.519	-3.451	-3.251	-3.011	-2.952
	Severe illness, 6 payment HCCs	-3.161	-2.997	-2.734	-2.401	-2.328
	Severe illness, 7 payment HCCs	-2.535	-2.249	-1.923	-1.504	-1.419
	Severe illness, 8 payment HCCs	-2.261	-1.896	-1.537	-1.036	-0.942
	Severe illness, 9 payment HCCs	-0.347	0.162	0.579	1.162	1.267
	Severe illness, 10 or more payment HCCs	6.494	7.367	7.904	8.706	8.837
	Transplant severe illness, 4 payment HCCs	3.479	3.363	3.296	3.168	3.138
	Transplant severe illness, 5 payment HCCs	6.565	6.435	6.380	6.259	6.233
	Transplant severe illness, 6 payment HCCs	10.720	10.578	10.529	10.408	10.380
	Transplant severe illness, 7 payment HCCs	14.798	14.641	14.590	14.473	14.448
	Transplant severe illness, 8 or more payment HCCs	30.301	30.241	30.218	30.135	30.110
Enrollment Duration Factors						
	Enrolled for 1 month, at least one payment HCC	11.551	10.110	9.201	8.280	8.111
	Enrolled for 2 months, at least one payment HCC	5.271	4.545	4.055	3.588	3.505
	Enrolled for 3 months, at least one payment HCC	3.355	2.883	2.542	2.223	2.168
	Enrolled for 4 months, at least one payment HCC	2.108	1.785	1.538	1.312	1.272
	Enrolled for 5 months, at least one payment HCC	1.583	1.343	1.152	0.975	0.942
	Enrolled for 6 months, at least one payment HCC	1.014	0.837	0.689	0.548	0.521
Prescription Drug Factors						
RXC 01	Anti-HIV Agents	5.080	4.590	4.301	3.855	3.786
RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.273	7.797	7.762	7.644	7.662

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 03 ^b	Antiarrhythmics	0.070	0.063	0.056	0.046	0.046
RXC 04	Phosphate Binders	0.920	1.051	0.885	1.053	1.217
RXC 05	Inflammatory Bowel Disease Agents	1.213	1.149	1.062	0.957	0.932
RXC 06	Insulin	1.345	1.183	1.021	0.860	0.827
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only	0.862	0.761	0.637	0.457	0.417
RXC 08	Multiple Sclerosis Agents	14.243	13.511	13.322	12.953	12.903
RXC 09	Immune Suppressants and Immunomodulators	11.920	11.394	11.363	11.214	11.227
RXC 10	Cystic Fibrosis Agents	20.797	20.324	20.299	20.170	20.180
RXC 01 x HCC001	Additional effect for enrollees with RXC 01 and HCC 001	2.337	2.374	2.650	2.960	3.040
RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.540	-0.480	-0.432	-0.378	-0.371
RXC 03 x HCC142	Additional effect for enrollees with RXC 03 and HCC 142	0.000	0.000	0.000	0.000	0.000
RXC 04 x HCC184, 183, 187, 188	Additional effect for enrollees with RXC 04 and (HCC 184 or 183 or 187 or 188)	0.000	0.000	0.000	0.000	0.000
RXC 05 x HCC048, 041	Additional effect for enrollees with RXC 05 and (HCC 048 or 041)	-0.868	-0.830	-0.781	-0.706	-0.690
RXC 06 x HCC018, 019, 020, 021	Additional effect for enrollees with RXC 06 and (HCC 018 or 019 or 020 or 021)	0.398	0.430	0.501	0.497	0.503
RXC 07 x HCC018, 019, 020, 021	Additional effect for enrollees with RXC 07 and (HCC 018 or 019 or 020 or 021)	-0.224	-0.181	-0.141	-0.101	-0.093
RXC 08 x HCC118	Additional effect for enrollees with RXC 08 and HCC 118	-0.686	-0.368	-0.134	0.196	0.274
RXC 09 x HCC056 or 057 and 048 or 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041) and (HCC 056 or 057)	0.441	0.500	0.552	0.628	0.644
RXC 09 x HCC056	Additional effect for enrollees with RXC 09 and HCC 056	-1.220	-1.126	-1.067	-0.987	-0.974
RXC 09 x HCC057	Additional effect for enrollees with RXC 09 and HCC 057	-0.361	-0.295	-0.220	-0.124	-0.104
RXC 09 x HCC048, 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041)	-0.104	-0.015	0.050	0.151	0.171
RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	42.842	42.900	42.986	43.095	43.118

a/ HCC numbers that appear with an underscore in this document will appear without the underscore in the DIY software. For example, HCC 35_1 in this table will appear as HCC 351 in the DIY software.

b/ We constrain RXC 03 to be equal to average plan liability for RXC 03 drugs, RXC 04 to be equal to the average plan liability for RXC 04 drugs, and we constrain RXC 03 x HCC142 and RXC 04 x HCC184, 183, 187, 188 to be equal to 0. See *March 2016 Risk Adjustment Methodology Discussion Paper* (March 24, 2016), available at <https://www.cms.gov/ccio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf> (where we previously discussed the use of constraints in the HHS risk adjustment models).

TABLE 5: Proposed Child HHS Risk Adjustment Model Factors for the 2026 Benefit Year

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2-4, Male	0.275	0.197	0.147	0.110	0.103
Age 5-9, Male	0.206	0.139	0.100	0.076	0.071
Age 10-14, Male	0.218	0.153	0.113	0.089	0.085
Age 15-20, Male	0.254	0.183	0.135	0.102	0.096
Age 2-4, Female	0.222	0.152	0.112	0.087	0.081
Age 5-9, Female	0.153	0.090	0.058	0.040	0.036
Age 10-14, Female	0.221	0.155	0.115	0.091	0.088
Age 15-20, Female	0.286	0.200	0.136	0.090	0.081
Diagnosis Factors					
HIV/AIDS	4.432	4.020	3.933	3.744	3.737
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	15.159	14.969	14.894	14.777	14.766
Central Nervous System Infections, Except Viral Meningitis	14.258	14.125	14.065	13.983	13.972
Viral or Unspecified Meningitis	13.861	13.735	13.667	13.575	13.559
Opportunistic Infections	19.550	19.503	19.430	19.350	19.333
Metastatic Cancer	31.112	30.879	30.817	30.711	30.704
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	9.342	9.119	9.022	8.874	8.855
Non-Hodgkin Lymphomas and Other Cancers and Tumors	8.439	8.247	8.142	7.988	7.963
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	4.086	3.946	3.864	3.740	3.716
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	4.086	3.946	3.864	3.740	3.716
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.309	1.199	1.105	0.987	0.963
Pancreas Transplant Status	12.114	12.103	12.087	12.074	12.069
Diabetes with Acute Complications	2.221	1.995	1.784	1.480	1.431
Diabetes with Chronic Complications	2.221	1.995	1.784	1.480	1.431
Diabetes without Complication	2.221	1.995	1.784	1.480	1.431
Protein-Calorie Malnutrition	19.116	19.000	18.960	18.905	18.898
Mucopolysaccharidosis	30.871	30.641	30.596	30.496	30.493
Lipidoses and Glycogenosis	30.871	30.641	30.596	30.496	30.493
Congenital Metabolic Disorders, Not Elsewhere Classified	4.743	4.634	4.577	4.500	4.489
Amyloidosis, Porphyria, and Other Metabolic Disorders	4.743	4.634	4.577	4.500	4.489
Adrenal, Pituitary, and Other Significant Endocrine Disorders	5.040	4.820	4.751	4.645	4.637
Liver Transplant Status/Complications	12.114	12.103	12.087	12.074	12.069
Acute Liver Failure/Disease, Including Neonatal Hepatitis	9.374	9.241	9.203	9.132	9.121
Chronic Liver Failure/End-Stage Liver Disorders	7.833	7.686	7.638	7.549	7.536
Cirrhosis of Liver	3.898	3.779	3.716	3.629	3.614
Chronic Viral Hepatitis C	1.186	1.081	1.008	0.923	0.907
Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.473	0.401	0.326	0.239	0.218

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Intestine Transplant Status/Complications	14.935	14.859	14.793	14.709	14.693
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	18.316	18.056	18.004	17.906	17.903
Intestinal Obstruction	4.523	4.352	4.262	4.128	4.109
Chronic Pancreatitis	8.313	8.165	8.114	8.016	8.002
Acute Pancreatitis	6.026	5.805	5.717	5.565	5.546
Inflammatory Bowel Disease	10.352	9.970	9.879	9.690	9.676
Necrotizing Fasciitis	4.288	4.095	4.002	3.869	3.852
Bone/Joint/Muscle Infections/Necrosis	4.288	4.095	4.002	3.869	3.852
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.773	4.527	4.447	4.318	4.307
Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.975	0.876	0.784	0.672	0.650
Osteogenesis Imperfecta and Other Osteodystrophies	1.213	1.112	1.041	0.953	0.939
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.213	1.112	1.041	0.953	0.939
Cleft Lip/Cleft Palate	0.884	0.761	0.665	0.541	0.519
Hemophilia	62.038	61.611	61.536	61.361	61.352
Myelodysplastic Syndromes and Myelofibrosis	12.776	12.620	12.565	12.477	12.468
Aplastic Anemia	12.776	12.620	12.565	12.477	12.468
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	12.776	12.620	12.565	12.477	12.468
Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero ^a	3.334	3.185	3.102	2.992	2.974
Sickle-Cell Disorders, Except Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major	3.334	3.185	3.102	2.992	2.974
Combined and Other Severe Immunodeficiencies	5.418	5.282	5.226	5.136	5.125
Disorders of the Immune Mechanism	5.418	5.282	5.226	5.136	5.125
Coagulation Defects and Other Specified Hematological Disorders	3.928	3.824	3.756	3.667	3.652
Drug Use with Psychotic Complications	2.337	2.195	2.104	1.972	1.949
Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	2.337	2.195	2.104	1.972	1.949
Alcohol Use with Psychotic Complications	0.778	0.650	0.545	0.397	0.373
Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	0.778	0.650	0.545	0.397	0.373
Schizophrenia	3.540	3.296	3.177	2.995	2.970
Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	3.132	2.909	2.778	2.582	2.553
Major Depressive Disorder, Severe, and Bipolar Disorders	2.588	2.398	2.271	2.101	2.073
Personality Disorders	0.458	0.375	0.273	0.158	0.133
Anorexia/Bulimia Nervosa	2.173	2.039	1.948	1.821	1.798
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	12.591	12.534	12.493	12.442	12.431
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	0.870	0.763	0.692	0.590	0.572
Autistic Disorder	2.588	2.398	2.271	2.101	2.073
Pervasive Developmental Disorders, Except Autistic Disorder	0.484	0.414	0.333	0.251	0.234
Traumatic Complete Lesion Cervical Spinal Cord	10.809	10.632	10.574	10.475	10.467
Quadriplegia	10.809	10.632	10.574	10.475	10.467

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Traumatic Complete Lesion Dorsal Spinal Cord	9.868	9.650	9.591	9.476	9.466
Paraplegia	9.868	9.650	9.591	9.476	9.466
Spinal Cord Disorders/Injuries	4.587	4.409	4.306	4.146	4.118
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	45.490	45.226	45.175	45.069	45.058
Quadriplegic Cerebral Palsy	0.831	0.651	0.579	0.461	0.449
Cerebral Palsy, Except Quadriplegic	0.381	0.266	0.204	0.124	0.109
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.523	1.414	1.350	1.252	1.237
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	10.844	10.706	10.684	10.631	10.630
Muscular Dystrophy	5.690	5.547	5.476	5.366	5.349
Multiple Sclerosis	7.657	7.323	7.253	7.109	7.103
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	5.690	5.547	5.476	5.366	5.349
Seizure Disorders and Convulsions	1.475	1.352	1.242	1.102	1.074
Hydrocephalus	12.442	12.383	12.338	12.292	12.280
Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic Brain Compression/Anoxic Damage	11.881	11.883	11.873	11.873	11.870
Narcolepsy and Cataplexy	4.158	4.015	3.919	3.783	3.752
Respirator Dependence/Tracheostomy Status	25.819	25.590	25.527	25.420	25.412
Respiratory Arrest	15.588	15.336	15.257	15.114	15.103
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	15.588	15.336	15.257	15.114	15.103
Heart Assistive Device/Artificial Heart	14.935	14.859	14.793	14.709	14.693
Heart Transplant Status/Complications	14.935	14.859	14.793	14.709	14.693
Heart Failure	3.788	3.690	3.638	3.557	3.542
Acute Myocardial Infarction	1.293	1.229	1.179	1.104	1.091
Unstable Angina and Other Acute Ischemic Heart Disease	1.293	1.229	1.179	1.104	1.091
Heart Infection/Inflammation, Except Rheumatic	15.964	15.860	15.788	15.694	15.675
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	3.733	3.594	3.485	3.351	3.326
Major Congenital Heart/Circulatory Disorders	0.957	0.868	0.769	0.670	0.651
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.487	0.406	0.327	0.251	0.238
Specified Heart Arrhythmias	3.007	2.866	2.784	2.671	2.654
Intracranial Hemorrhage	12.917	12.857	12.829	12.790	12.784
Ischemic or Unspecified Stroke	1.196	1.087	1.028	0.938	0.926
Cerebral Aneurysm and Arteriovenous Malformation	0.788	0.690	0.638	0.553	0.537
Hemiplegia/Hemiparesis	5.113	4.995	4.936	4.846	4.836
Monoplegia, Other Paralytic Syndromes	2.053	1.940	1.874	1.773	1.757
Atherosclerosis of the Extremities with Ulceration or Gangrene	10.494	10.279	10.205	10.071	10.061
Vascular Disease with Complications	10.563	10.421	10.369	10.279	10.271
Pulmonary Embolism and Deep Vein Thrombosis	20.314	20.192	20.129	20.039	20.025
Lung Transplant Status/Complications	14.935	14.859	14.793	14.709	14.693
Cystic Fibrosis	51.368	50.854	50.808	50.658	50.665
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	1.574	1.429	1.324	1.188	1.165

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Severe Asthma	1.300	1.150	1.025	0.871	0.843
Asthma, Except Severe	0.315	0.248	0.171	0.105	0.091
Fibrosis of Lung and Other Lung Disorders	1.467	1.341	1.229	1.097	1.072
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	11.748	11.771	11.801	11.852	11.859
Kidney Transplant Status/Complications	12.114	12.103	12.087	12.074	12.069
End Stage Renal Disease	25.623	25.420	25.403	25.337	25.332
Chronic Kidney Disease, Stage 5	0.853	0.779	0.729	0.672	0.665
Chronic Kidney Disease, Severe (Stage 4)	0.853	0.779	0.729	0.672	0.665
Ectopic and Molar Pregnancy	0.755	0.625	0.472	0.330	0.308
Miscarriage with Complications	0.389	0.294	0.158	0.035	0.011
Miscarriage with No or Minor Complications	0.389	0.294	0.158	0.035	0.011
Pregnancy with Delivery with Major Complications	3.064	2.797	2.554	2.151	2.065
Pregnancy with Delivery with Complications	3.064	2.797	2.554	2.151	2.065
Pregnancy with Delivery with No or Minor Complications	2.183	1.985	1.734	1.324	1.218
(Ongoing) Pregnancy without Delivery with Major Complications	0.420	0.308	0.145	0.014	0.000
(Ongoing) Pregnancy without Delivery with Complications	0.420	0.308	0.145	0.014	0.000
(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.210	0.128	0.027	0.000	0.000
Chronic Ulcer of Skin, Except Pressure	2.287	2.195	2.121	2.041	2.027
Extensive Third-Degree Burns	22.632	22.402	22.326	22.204	22.186
Major Skin Burn or Condition	2.587	2.430	2.328	2.189	2.168
Severe Head Injury	22.632	22.402	22.326	22.204	22.186
Hip and Pelvic Fractures	4.602	4.393	4.289	4.153	4.136
Vertebral Fractures without Spinal Cord Injury	4.311	4.117	4.000	3.829	3.802
Traumatic Amputations and Amputation Complications	4.308	4.125	4.026	3.865	3.835
Stem Cell, Including Bone Marrow, Transplant Status/Complications	14.935	14.859	14.793	14.709	14.693
Artificial Openings for Feeding or Elimination	5.156	4.991	4.958	4.879	4.875
Amputation Status, Upper Limb or Lower Limb	4.308	4.125	4.026	3.865	3.835
Interacted HCC Counts Factors					
Severe illness, 1 payment HCC	-11.721	-11.771	-11.801	-11.852	-11.859
Severe illness, 2 payment HCCs	-11.721	-11.771	-11.801	-11.852	-11.859
Severe illness, 3 payment HCCs	-10.550	-10.621	-10.563	-10.542	-10.525
Severe illness, 4 payment HCCs	-9.240	-9.248	-9.085	-8.937	-8.892
Severe illness, 5 payment HCCs	-8.082	-8.043	-7.823	-7.606	-7.548
Severe illness, 6 or 7 payment HCCs	-3.581	-3.360	-3.017	-2.629	-2.542
Severe illness, 8 or more payment HCCs	16.144	16.838	17.409	18.129	18.259
Transplant severe illness, 4 or more payment HCCs	13.212	13.245	13.253	13.269	13.271

TABLE 6: Proposed HCCs Selected for the HCC Interacted Counts Variables for the HHS Risk Adjustment Adult and Child Models for the 2026 Benefit Year

Payment HCC	Severity Illness Indicator	Transplant Indicator
HCC 2 Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	X	
HCC 3 Central Nervous System Infections, Except Viral Meningitis	X	
HCC 4 Viral or Unspecified Meningitis	X	
HCC 6 Opportunistic Infections	X	
HCC 23 Protein-Calorie Malnutrition	X	
HCC 34 Liver Transplant Status/Complications	X	X
HCC 41 Intestine Transplant Status/Complications	X	X
HCC 42 Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	X	
HCC 96 Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	X	
HCC 121 Hydrocephalus	X	
HCC 122 Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic Brain Compression/Anoxic Damage	X	
HCC 125 Respirator Dependence/Tracheostomy Status	X	
HCC 135 Heart Infection/Inflammation, Except Rheumatic	X	
HCC 145 Intracranial Hemorrhage	X	
HCC 156 Pulmonary Embolism and Deep Vein Thrombosis	X	
HCC 158 Lung Transplant Status/Complications	X	X
HCC 163 Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	X	
HCC 218 Extensive Third-Degree Burns	X	
HCC 223 Severe Head Injury	X	
HCC 251 Stem Cell, Including Bone Marrow, Transplant Status/Complications	X	X
G13 (Includes HCC 126 Respiratory Arrest and HCC 127 Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes)	X	
G14 (Includes HCC 128 Heart Assistive Device/Artificial Heart and HCC 129 Heart Transplant Status/Complications)	X	X
G24 (Includes HCC 18 Pancreas Transplant Status and HCC 183 Kidney Transplant Status/Complications)	X	X

TABLE 7: Proposed Infant HHS Risk Adjustment Model Factors for the 2026 Benefit Year

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	202.124	200.721	200.443	199.930	199.923
Extremely Immature * Severity Level 4	135.710	134.101	133.672	132.966	132.922
Extremely Immature * Severity Level 3	31.009	29.686	29.283	28.690	28.647
Extremely Immature * Severity Level 2	31.009	29.686	29.283	28.690	28.647
Extremely Immature * Severity Level 1 (Lowest)	31.009	29.686	29.283	28.690	28.647
Immature * Severity Level 5 (Highest)	129.458	128.096	127.837	127.350	127.343
Immature * Severity Level 4	68.163	66.651	66.320	65.727	65.699
Immature * Severity Level 3	31.009	29.686	29.283	28.690	28.647
Immature * Severity Level 2	26.411	25.209	24.810	24.230	24.181
Immature * Severity Level 1 (Lowest)	23.143	21.917	21.486	20.866	20.806
Premature/Multiples * Severity Level 5 (Highest)	110.758	109.418	109.135	108.626	108.606
Premature/Multiples * Severity Level 4	28.791	27.494	27.114	26.514	26.473
Premature/Multiples * Severity Level 3	12.969	12.062	11.572	10.902	10.797
Premature/Multiples * Severity Level 2	7.878	7.175	6.664	5.992	5.863
Premature/Multiples * Severity Level 1 (Lowest)	5.519	4.934	4.429	3.846	3.726
Term * Severity Level 5 (Highest)	81.499	80.353	80.008	79.461	79.415
Term * Severity Level 4	16.505	15.543	15.080	14.433	14.351
Term * Severity Level 3	5.467	4.914	4.413	3.825	3.702
Term * Severity Level 2	3.655	3.183	2.680	2.112	1.991
Term * Severity Level 1 (Lowest)	1.955	1.593	1.156	0.813	0.752
Age1 * Severity Level 5 (Highest)	67.661	66.998	66.818	66.533	66.516
Age1 * Severity Level 4	12.321	11.828	11.591	11.279	11.240
Age1 * Severity Level 3	2.767	2.515	2.325	2.133	2.100
Age1 * Severity Level 2	1.792	1.572	1.374	1.176	1.136
Age1 * Severity Level 1 (Lowest)	0.576	0.485	0.431	0.396	0.389
Age 0 Male	0.606	0.569	0.541	0.484	0.471
Age 1 Male	0.074	0.060	0.044	0.025	0.021

TABLE 8: Proposed HHS HCCs Included in HHS Risk Adjustment Infant Model Maturity Categories for 2026 Benefit Year

Maturity Category	HCC/Description
Extremely Immature	Extremely Immature Newborns, Birth weight < 500 Grams
Extremely Immature	Extremely Immature Newborns, Including Birth weight 500-749 Grams
Extremely Immature	Extremely Immature Newborns, Including Birth weight 750-999 Grams
Immature	Premature Newborns, Including Birth weight 1000-1499 Grams
Immature	Premature Newborns, Including Birth weight 1500-1999 Grams
Premature/Multiples	Premature Newborns, Including Birth weight 2000-2499 Grams
Premature/Multiples	Other Premature, Low Birth weight, Malnourished, or Multiple Birth Newborns
Term	Term or Post-Term Singleton Newborn, Normal or High Birth weight
Age 1	All age 1 infants

TABLE 9: Proposed HHS HCCs Included in HHS Risk Adjustment Infant Model Severity Categories for 2026 Benefit Year

Severity Category	HCC/Description
Severity Level 5 (Highest)	Metastatic Cancer
Severity Level 5	Pancreas Transplant Status
Severity Level 5	Liver Transplant Status/Complications
Severity Level 5	Intestine Transplant Status/Complications
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis
Severity Level 5	Respirator Dependence/Tracheostomy Status
Severity Level 5	Heart Assistive Device/Artificial Heart
Severity Level 5	Heart Transplant Status/Complications
Severity Level 5	Heart Failure
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders
Severity Level 5	Lung Transplant Status/Complications
Severity Level 5	Kidney Transplant Status/Complications
Severity Level 5	End Stage Renal Disease
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia
Severity Level 4	Mucopolysaccharidosis
Severity Level 4	Adrenal, Pituitary, and Other Significant Endocrine Disorders
Severity Level 4	Acute Liver Failure/Disease, Including Neonatal Hepatitis
Severity Level 4	Chronic Liver Failure/End-Stage Liver Disorders
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age < 2
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis
Severity Level 4	Aplastic Anemia
Severity Level 4	Combined and Other Severe Immunodeficiencies
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord
Severity Level 4	Quadriplegia
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease
Severity Level 4	Quadriplegic Cerebral Palsy
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy
Severity Level 4	Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic Brain Compression/Anoxic Damage
Severity Level 4	Respiratory Arrest
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
Severity Level 4	Acute Myocardial Infarction
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic
Severity Level 4	Major Congenital Heart/Circulatory Disorders

Severity Category	HCC/Description
Severity Level 4	Intracranial Hemorrhage
Severity Level 4	Ischemic or Unspecified Stroke
Severity Level 4	Vascular Disease with Complications
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections
Severity Level 4	Chronic Kidney Disease, Stage 5
Severity Level 4	Artificial Openings for Feeding or Elimination
Severity Level 3	HIV/AIDS
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis
Severity Level 3	Opportunistic Infections
Severity Level 3	Non-Hodgkin Lymphomas and Other Cancers and Tumors
Severity Level 3	Colorectal, Breast (Age < 50), Kidney and Other Cancers
Severity Level 3	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors
Severity Level 3	Lipidoses and Glycogenosis
Severity Level 3	Intestinal Obstruction
Severity Level 3	Necrotizing Fasciitis
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies
Severity Level 3	Cleft Lip/Cleft Palate
Severity Level 3	Hemophilia
Severity Level 3	Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero
Severity Level 3	Disorders of the Immune Mechanism
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders
Severity Level 3	Drug Use with Psychotic Complications
Severity Level 3	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications
Severity Level 3	Alcohol Use with Psychotic Complications
Severity Level 3	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord
Severity Level 3	Paraplegia
Severity Level 3	Spinal Cord Disorders/Injuries
Severity Level 3	Cerebral Palsy, Except Quadriplegic
Severity Level 3	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies
Severity Level 3	Muscular Dystrophy
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders
Severity Level 3	Hydrocephalus
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders
Severity Level 3	Specified Heart Arrhythmias
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation
Severity Level 3	Hemiplegia/Hemiparesis
Severity Level 3	Cystic Fibrosis
Severity Level 3	Extensive Third-Degree Burns
Severity Level 3	Severe Head Injury
Severity Level 3	Hip and Pelvic Fractures
Severity Level 3	Vertebral Fractures without Spinal Cord Injury
Severity Level 2	Viral or Unspecified Meningitis
Severity Level 2	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors
Severity Level 2	Diabetes with Acute Complications
Severity Level 2	Diabetes with Chronic Complications
Severity Level 2	Diabetes without Complication
Severity Level 2	Protein-Calorie Malnutrition
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders
Severity Level 2	Cirrhosis of Liver

Severity Category	HCC/Description
Severity Level 2	Chronic Pancreatitis
Severity Level 2	Acute Pancreatitis
Severity Level 2	Inflammatory Bowel Disease
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn
Severity Level 2	Sickle-Cell Disorders, Except Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes
Severity Level 2	Seizure Disorders and Convulsions
Severity Level 2	Monoplegia, Other Paralytic Syndromes
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis
Severity Level 2	Severe Asthma
Severity Level 2	Fibrosis of Lung and Other Lung Disorders
Severity Level 2	Chronic Kidney Disease, Severe (Stage 4)
Severity Level 2	Chronic Ulcer of Skin, Except Pressure
Severity Level 2	Major Skin Burn or Condition
Severity Level 1 (Lowest)	Chronic Viral Hepatitis C
Severity Level 1	Chronic Hepatitis, Except Chronic Viral Hepatitis C
Severity Level 1	Autistic Disorder
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder
Severity Level 1	Multiple Sclerosis
Severity Level 1	Asthma, Except Severe
Severity Level 1	Traumatic Amputations and Amputation Complications
Severity Level 1	Amputation Status, Upper Limb or Lower Limb

BILLING CODE 4120-01-C**e. Cost-Sharing Reduction Adjustments**

In the 2025 Payment Notice (89 FR 26252 through 26254), we finalized the updated CSR adjustment factors for American Indian/Alaska Native (AI/AN) zero-cost sharing and limited cost sharing CSR plan variant enrollees for the 2025 benefit year, and for all future benefit years, unless changed through notice-and-comment rulemaking. In the 2025 Payment Notice (89 FR 26252 through 26254), we also finalized maintaining the existing CSR adjustment factors for silver plan variant enrollees (70 percent, 73 percent, 87 percent, and 94 percent AV plan variants)⁷⁵ for the 2025 benefit year and beyond, unless changed through notice-and-comment rulemaking. Under this approach, we will no longer republish these factors in future annual HHS notice of benefit and payment parameter

rules unless changes are being proposed.

For the 2026 benefit year, we are not proposing to change the CSR adjustment factors as finalized in the 2025 Payment Notice and will maintain the existing CSR adjustment factors for the 2026 benefit year. Since we are not proposing any changes to the CSR adjustment factors for the 2026 benefit year, we are not republishing the CSR adjustment factors in this rule.⁷⁶

f. Model Performance Statistics

Each benefit year, to evaluate the HHS risk adjustment model performance, we examine each model's R-squared statistic and predictive ratios (PRs). The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The PR for each of the HHS risk adjustment 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 current and proposed HHS risk adjustment models, the R-squared statistic and the PRs are in the range of published estimates for concurrent HHS risk adjustment models.⁷⁷ Because we propose to blend the coefficients from separately solved models based on the 2020, 2021 and 2022 benefit years' enrollee-level EDGE data, we are publishing the R-squared statistic for each model separately to verify their statistical validity. The R-squared statistics for the proposed 2026 benefit HHS risk adjustment models are shown in table 10.

⁷⁵ See 83 FR 16930 at 16953; 84 FR 17478 through 17479; 85 FR 29190; 86 FR 24181; 87 FR 27235 through 27236; 88 FR 25772 through 25774; and 89 FR 26252 through 26254.

⁷⁶ See CSR adjustment factors finalized in the 2025 Payment Notice at 89 FR 26252 through 26254.

⁷⁷ Hileman, G., & Steele, S. (2016). *Accuracy of Claims-Based Risk Scoring Models*. Society of Actuaries. <https://www.soa.org/4937b5/globalassets/assets/files/research/research-2016-accuracy-claims-based-risk-scoring-models.pdf>.

TABLE 10: R-Squared Statistic for the Proposed 2026 HHS Risk Adjustment Models

Models	2020 Enrollee-Level EDGE Data	2021 Enrollee-Level EDGE Data	2022 Enrollee-Level EDGE Data
Platinum Adult	0.4377	0.4187	0.4067
Gold Adult	0.4317	0.4129	0.4007
Silver Adult	0.4293	0.4105	0.3980
Bronze Adult	0.4252	0.4063	0.3936
Catastrophic Adult	0.4246	0.4057	0.3928
Platinum Child	0.3453	0.3554	0.3620
Gold Child	0.3421	0.3526	0.3594
Silver Child	0.3401	0.3506	0.3574
Bronze Child	0.3371	0.3476	0.3544
Catastrophic Child	0.3365	0.3470	0.3537
Platinum Infant	0.2928	0.3072	0.2862
Gold Infant	0.2892	0.3037	0.2827
Silver Infant	0.2878	0.3023	0.2813
Bronze Infant	0.2856	0.3000	0.2790
Catastrophic Infant	0.2853	0.2997	0.2787

3. Overview of the HHS Risk Adjustment Methodology: State Payment Transfer Formula

In part 2 of the 2022 Payment Notice (86 FR 24183 through 24186), we finalized the proposal to continue to use the State payment transfer formula finalized in the 2021 Payment Notice for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking. We explained that under this approach, we will no longer republish these formulas in future annual HHS notice of benefit and payment parameters rules unless changes are being proposed. We are not proposing any changes to the formula in this rule, and therefore, are not republishing the formulas in this rule. We therefore would continue to apply the formula as finalized in the 2021 Payment Notice (86 FR 24183 through 24186) in the States where HHS operates the risk adjustment program in the 2026 benefit year.

Additionally, as finalized in the 2020 Payment Notice (84 FR 17466 through 17468), we will maintain the high-cost risk pool parameters for the 2020 benefit year and beyond, unless amended through notice-and-comment rulemaking. We are not proposing any changes to the high-cost risk pool parameters for the 2025 benefit year; therefore, we would maintain the \$1 million threshold and 60 percent coinsurance rate.⁷⁸

4. Solicitation of Comments—Time Value of Money in HHS-Operated Risk Adjustment Program

HHS received feedback from some interested parties that, for the 2023 benefit year, issuers of risk adjustment covered plans were impacted more by the time value of money, for the collection and remittance of State transfers that occurs 8 to 10 months after the conclusion of the benefit year,⁷⁹ than in any previous benefit years of the HHS-operated risk adjustment program. Given that interest rates were the highest in 2023 than in any year since the passage of the ACA, the impact of the time value of money has changed and is higher than it has been historically. We therefore solicit comments on what impact the time value of money may have on issuers' assessment of actuarial risk and incentives for adverse selection.

Unlike Medicare Advantage's risk adjustment program, under which CMS makes risk-adjusted monthly payments to Medicare Advantage organizations during the coverage year (in advance of each month of coverage) using interim risk scores and then does a reconciliation to updated risk scores after the final deadline for submission of all risk adjustment data, the HHS-operated risk adjustment program for the individual, small group and merged markets uses a final data submission

deadline 4 months after the end of the benefit year and calculates issuers' plan liability risk scores and the State transfer amounts 2 months after that, resulting in State transfers being made 8 to 10 months after the end of the benefit year.⁸⁰ HHS typically announces State transfer amounts no later than June 30 of the year following the benefit year,⁸¹ begins to collect charges in August of the year following the benefit year, and begins to make payments to issuers in the fall of the year following the applicable benefit year. This process means that issuers whose enrollees have higher-than-average actuarial risk do not receive their State transfer payments until the fall of the year following the benefit year. Over this same time period, issuers whose enrollees have lower-than-average actuarial risk are able to benefit from the availability of capital from the collection of premiums for

⁸⁰ The EDGE data submission deadline is April 30, or if such date is not a business day, the next applicable business day. See 45 CFR 153.730. We note that the deadline for submission of 2023 benefit year data was extended to provide issuers flexibility in managing the challenges associated with the Change HealthCare cybersecurity incident and its impact on risk adjustment covered plans. See *CMS Announcement BY2023 EDGE Data Submission MLR Extension* https://www.cms.gov/ccio/resources/regulations-and-guidance/downloads/by_2023_announcement_edge_data_submission_mlr_extension.pdf.

⁸¹ Risk adjustment transfer amounts are typically announced no later than June 30, or if such date is not a business day, the next applicable business day. See 45 CFR 153.310(e). The date for announcement of transfer amounts for the 2023 benefit year was extended in recognition of the extension of the deadline for EDGE data submissions. See *supra* note 92. After transfer amounts for a benefit year are announced, collection of charges typically begins in August with payments beginning in September.

⁷⁸ See 81 FR 94081. See also 84 FR 17467.

⁷⁹ Charges are typically sent out in August in the year after the benefit year and the majority of payments typically made in September and October in the year after the benefit year; payments held for sequestration from charges collected prior to October 1st are released in November of the same year.

investment that could accrue interest between the benefit year and when the collection of charges begins in August of the year following the benefit year, which we refer to as the “time value of money.”

To continue to ensure appropriate incentives exist in the individual, small group, and merged markets to cover both healthy and sick enrollees, we believe that this market dynamic, the time value of money, and its potential impact on actuarial risk and adverse selection should be discussed and considered. Consistent with section 1343 of the ACA, in States where HHS is responsible for operating the program,⁸² we calculate average actuarial risk to assess charges to issuers with risk adjustment covered plans with lower-than-average actuarial risk and to make payments to issuers with risk adjustment covered plans with higher-than-average actuarial risk. The ACA’s permanent risk adjustment program for the individual, small group, and merged markets is intended to minimize the incentives for adverse selection, to help level the playing field between insurance companies, and to foster a stable market in which issuers provide coverage to individuals with higher health care costs and those who are sick have access to the coverage they need.

The impact of the time value of money has increased to levels significantly higher than those seen in the initial years after the passage of the ACA. For example, in January 2016, the annual short-term Applicable Federal Rate (AFR) interest rate was 0.75 percent, whereas in January 2023 the AFR interest rate had increased to 4.50 percent.⁸³ This increase in the time value of money could impact the individual, small group, and merged markets by changing the incentives faced by issuers enrolling lower-than-average risk populations rather than higher-than-average risk populations, as lower-risk populations not only have lower claims costs, but could result in potential accrued interest for their premium revenues, whereas issuers with higher-risk populations are expected to incur higher claims costs and would generally not be able to collect the potential accrued interest for their premium revenues. To further

illustrate this issue, in a hypothetical State market risk pool with only two issuers, where the risk adjustment issuer with lower-risk enrollees owes a \$1,000,000 charge and the risk adjustment issuer with higher-risk enrollees receives a payment of \$1,000,000, the charge issuer may have accrued an additional \$45,000 in interest from the initial \$1,000,000, and after paying the risk adjustment charge, would retain the \$45,000, while the payment issuer is deprived of the same opportunity. Thus, we have received feedback from interested parties expressing concern about this scenario in the context of the HHS-operated risk adjustment program and concerns about how it could create incentives for adverse selection that could result in issuers that receive State transfer payments raising premiums to recoup lost opportunity costs from the time value of money.

For these reasons, we solicit comments on the impact of the time value of money on the HHS-operated risk adjustment program, including the impact of the time value of money on issuers’ assessment of actuarial risk and the incentives for adverse selection, and what possible solutions or mitigating steps we should consider to address the impact of the time value of money on the HHS-operated risk adjustment program in future rulemaking.

5. HHS Risk Adjustment User Fee for the 2026 Benefit Year (§ 153.610(f))

We propose an HHS risk adjustment user fee for the 2026 benefit year of \$0.18 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. For the 2026 benefit year, HHS will operate risk adjustment in every State and the District of Columbia. As described in the 2014 Payment Notice (78 FR 15416 through 15417), HHS’ operation of the risk adjustment program on behalf of States is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that, where HHS operates a risk adjustment program on behalf of a State, an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the PMPM risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A–25 established Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable

recipient for special benefits derived from Federal activities beyond those received by the general public.⁸⁴ The HHS-operated risk adjustment program provides special benefits as defined in section 6(a)(1)(B) of OMB Circular No. A–25 to issuers of risk adjustment covered plans because it mitigates the financial instability associated with potential adverse risk selection.⁸⁵ The HHS-operated risk adjustment program also contributes to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual, merged, and small group markets.

In the 2025 Payment Notice (89 FR 26218), we calculated the Federal administrative expenses of operating the HHS risk adjustment program for the 2025 benefit year to result in a risk adjustment user fee rate of \$0.18 PMPM based on our estimated costs for HHS risk adjustment operations and estimated billable member months (BMM) for individuals enrolled in risk adjustment covered plans. For the 2026 benefit year, HHS proposes to use the same methodology to estimate our administrative expenses to operate the program. These costs cover development of the models and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, interested parties training, operational support, and administrative and personnel costs dedicated to HHS-operated risk adjustment program activities. To calculate the risk adjustment user fee, we divided HHS’ projected total costs for administering the program on behalf of States by the expected number of BMM in risk adjustment covered plans in States where the HHS-operated risk adjustment program will apply in the 2026 benefit year.⁸⁶

We estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for the 2026 benefit year will be approximately \$65 million, roughly the same as the amount estimated for the 2025 benefit year.

Similar to prior benefit years, we projected risk adjustment enrollment scenarios for the 2026 benefit year. For the 2021 through 2025 benefit years, we projected increased enrollment in the

⁸² Section 1321(c)(1) of the ACA directs the HHS Secretary to operate the risk adjustment program in any State that fails to elect to do so. Since the 2017 benefit year, HHS has operated the program in all 50 States and the District of Columbia.

⁸³ The IRS publishes all annual short-term AFRs at: <https://www.irs.gov/applicable-federal-rates>. January 2016 AFR: <https://www.irs.gov/pub/irs-drop/r-16-01.pdf>; January 2023 AFR: <https://www.irs.gov/pub/irs-drop/r-23-01.pdf>.

⁸⁴ See Circular No. A–25 Revised. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>.

⁸⁵ *Ibid.*

⁸⁶ HHS did not receive any requests from States to operate risk adjustment for the 2026 benefit year. Therefore, HHS will operate risk adjustment in every State and the District of Columbia for the 2026 benefit year.

individual non-catastrophic market risk pool in most States, due to the enhanced PTC subsidies provided for in the American Rescue Plan Act of 2021 (ARP)^{87 88} and the extension of the enhanced PTC subsidies under Section 12001 of the Inflation Reduction Act of 2022 (IRA) through the 2025 benefit year.⁸⁹ For our 2026 user fee projected enrollment numbers, we considered the impact of the expiration of the enhanced PTC subsidies established in section 9661 of the ARP and extended in section 12001 of the IRA through the 2025 benefit year on the enrollment in the individual, small group, and merged market risk pools for the 2026 benefit year and used those estimates to project the proposed 2026 benefit year HHS risk adjustment user fee rate. We also note that if any events such as Congress passing an extension of enhanced PTC subsidies, resulting in larger than expected growth in individual on Exchange enrollment or some other deviation from our expectations of current conditions that would significantly change our estimates around costs, enrollment projections, or the finalization of proposed risk adjustment policies between this proposed rule and the final rule, we may modify the HHS risk adjustment user fee rate proposed in this rule in the final rule. Because we project a similar budget to operate the HHS-operated risk adjustment program and do not estimate increased enrollment in the 2026 benefit year beyond the 2024 benefit year level, we propose an HHS risk adjustment user fee of \$0.18 PMPM for the 2026 benefit year.

We seek comment on the proposed HHS risk adjustment user fee for the 2026 benefit year.

6. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (HHS–RADV) (§§ 153.350 and 153.630)

HHS conducts risk adjustment data validation under §§ 153.350 and 153.630 in any State where HHS is responsible for operating the risk adjustment program.⁹⁰ The purpose of risk adjustment data validation is to ensure issuers are providing accurate high-quality information to HHS, which is crucial for the proper functioning of the

HHS-operated risk adjustment program. HHS–RADV also ensures that risk adjustment transfers calculated under the State payment transfer formula reflect verifiable actuarial risk differences among issuers, rather than risk score calculations that are based on poor quality data, thereby helping to ensure that the HHS-operated risk adjustment program assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk. HHS–RADV consists of an initial validation audit (IVA) and a second validation audit (SVA). Under § 153.630, each issuer of a risk adjustment covered plan must engage an IVA entity. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to its IVA entity for data validation. Each issuer's IVA is followed by an SVA, which is conducted by an entity HHS retains to verify the accuracy of the findings of the IVA. Based on the findings from the IVA, or SVA (as applicable), HHS conducts error estimation to calculate an HHS–RADV error rate. The HHS–RADV error rate is then applied to adjust the plan liability risk scores of outlier issuers, as well as the risk adjustment transfers calculated under the State payment transfer formula for the applicable State market risk pools, for the benefit year being audited.

a. Initial Validation Audit (IVA) Sampling Methodology—Enrollees Without HCCs, Finite Population Correction, and Neyman Allocation (§ 153.630(b))

To better align the IVA sampling methodology with the HHS–RADV error estimation methodology that estimates hierarchical condition categories (HCC) error rates and to improve overall sampling precision, we are proposing to exclude enrollees without HCCs⁹¹ from IVA sampling, to remove the Finite Population Correction (FPC), and to replace the source of the Neyman allocation⁹² data used for IVA sampling purposes with 3 years of available HHS–

RADV data beginning with benefit year 2025 HHS–RADV.⁹³

1. IVA Sampling Background

HHS–RADV IVA sampling policy was originally described in the 2014 Payment Notice (78 FR 15436) where we stated that HHS would choose a sample size of enrollees for HHS–RADV such that the estimated risk score errors would be statistically sound, and the enrollee-level risk score distributions would reflect enrollee characteristics for each issuer. To implement this approach, in the 2015 Payment Notice (79 FR 13756 through 13758), we finalized two key aspects of the IVA sampling methodology. First, HHS set the IVA sample size as 200 enrollees per issuer, as sample size precision analyses performed at the time with data available from Medicare Advantage RADV (MA–RADV) program, which utilizes a similar HCC-based methodology as the HHS–RADV methodology, indicated that a sample size of 200 enrollees would achieve the targeted precision for an average sized issuer and that there would be no meaningful improvement in the estimated level of precision with larger sample sizes. In particular, to establish this 200-enrollee sample, we set a 10 percent sampling precision target at a two-sided 95 percent confidence level. That is, we aimed to obtain a sample size such that 1.96 multiplied by the standard error, divided by the estimated adjusted risk score, equals 10 percent or less.^{94 95} To translate this policy to small issuers, we established an FPC factor to calculate a modified IVA sample size smaller than 200 enrollees.⁹⁶ If an issuer

⁹³ Activities related to the 2025 benefit year of HHS–RADV will generally begin in Spring 2026, when issuers can start selecting their IVA entity, and IVA entities can start electing to participate in HHS–RADV for the 2025 benefit year. Changes to the IVA sampling methodology need to be finalized before HHS–RADV activities begin; therefore, we are proposing these IVA sampling changes begin with 2025 benefit year HHS–RADV due to the timing of this rulemaking. For an example of the typical annual HHS–RADV timeline, see the *2023 Benefit Year HHS–RADV Activities Timeline*, https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.

⁹⁴ See 79 FR 13756 through 13758. Also see CMS. (2013). *Affordable Care Act (ACA) HHS-Operated Risk Adjustment Data Validation (RADV) Process White Paper*. (pp. 26–28). https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ACA_HHS_OperatedRADVWhitePaper_062213_5CR_050718.pdf.

⁹⁵ We established this sampling precision target in the initial year of HHS–RADV based on a survey of guidance from the OMB, Internal Revenue Service (IRS), and the HHS-developed Payment Error Rate Measurement (PERM) program.

⁹⁶ An FPC is traditionally used when sampling without replacement from a finite population and the sample size, *n*, is significant in comparison with the population size, *N*.

Continued

⁸⁷ ARP. Public Law 117–2 (2021).

⁸⁸ CMS. (2023). *Summary Report on Permanent Risk Adjustment Transfers for the 2022 Benefit Year*. (p. 8). <https://www.cms.gov/files/document/summary-report-permanent-risk-adjustment-transfers-2022-benefit-year.pdf>.

⁸⁹ Inflation Reduction Act. Public Law 1217–169 (2022).

⁹⁰ Since the 2017 benefit year, HHS has operated the risk adjustment program in all 50 States and the District of Columbia.

⁹¹ Adult enrollees with only RXCs do not have any HCCs, and therefore, as further explained in this preamble, would be excluded from IVA sampling under this proposal.

⁹² Neyman allocation is a method to allocate samples to strata based on the strata variances. A Neyman allocation scheme provides the most precision for estimating a population mean given a fixed total sample size. See <http://methods.sagepub.com/reference/encyclopedia-of-survey-research-methods/n324.xml>.

has between 51 and 3,999 enrollees, the issuer's IVA sample size is calculated by multiplying the FPC factor, which is a factor less than one, by the standard sample size of 200.⁹⁷ If an issuer has 50 or fewer enrollees, its sample size is equal to its enrollment. Second, the policies finalized in the 2015 Payment Notice established that the IVA sampling methodology would use a simple age and risk score stratification that categorizes the relevant population into 10 strata, representing different demographic and risk score bands, and use a Neyman allocation sampling methodology to select an issuer's IVA sample for a given benefit year.^{98 99 100} This stratified design was intended to ensure adequate sample selection of the higher risk portion of the enrollee population and the Neyman allocation increases the likelihood that the sample achieves targeted levels of precision because strata with greater variance will be sampled more heavily.¹⁰¹

Under the current risk score stratification in IVA sampling, to align with the HHS-operated risk adjustment program's three separate models for adult, child, and infants, we group each issuer's enrollee population into 10 strata based on age group, risk level, and presence of HCCs and prescription drug factors (RXC) ¹⁰² as follows:

- Strata 1–3 includes low, medium, and high risk adults with the presence of at least one HCC or RXC.
- Strata 4–6 includes low, medium, and high risk children with the presence of at least one HCC.
- Strata 7–9 includes low, medium, and high risk infants with the presence of at least one HCC.
- Stratum 10 includes the No-HCC and No-RXC population, which is not further stratified by age group, because we assume this stratum has a uniformly low risk level.

The current IVA sampling methodology relies on MA–RADV proxy data to conduct the Neyman allocation, which optimizes stratum sample size by selecting the number of enrollees to be sampled from each of the 10 strata, listed above, that is proportional to each stratum's contribution to the total standard deviation of the population.¹⁰³ The Neyman allocation formula for the overall sample size for each stratum of the issuer's IVA sample ($n_{i,h}$) is:

$$n_{i,h} = n_i * \frac{N_{i,h} S_{i,h}}{\sum_{h=1}^H N_{i,h} S_{i,h}}$$

Where:

- $N_{i,h}$ is the population size of the h^{th} stratum of issuer i .
- n_i is the IVA sample size of issuer i .
- H is the total number of strata.
- $S_{i,h}$ represents the standard deviation of risk score error amount for the h^{th} stratum.

As described in the 2015 Payment Notice (79 FR 13756 through 13758), we use MA–RADV data to calculate the standard deviation of risk score error ($S_{i,h}$) across all 10 strata. At the time, we chose to use MA–RADV data when establishing the Neyman allocation because HHS–RADV data was not available and the MA–RADV program utilizes a similar HCC-based methodology. Because MA–RADV data does not have child or infant age groups, we can only calculate a single standard deviation of risk score error for each risk-score subgrouping (low, medium and high). Therefore, to use the MA–RADV data, we assume that the standard deviation of risk score error within a risk-score subgrouping is the same for each of the three age groups (adult, child, and infant) in the HHS–RADV population. Given our assumptions on the strata net risk score errors and variances from the MA–RADV data, we found that 200 enrollees

would be an appropriate IVA sample size to achieve 10 percent sampling precision for net risk score error for an average-sized issuer. We also explained that we intended to test and evaluate HHS–RADV data for use for this purpose in future years when it became available.¹⁰⁴

HHS–RADV error estimation has been modified over time without making corresponding changes to the IVA sampling methodology. For example, in the 2019 Payment Notice (83 FR 16961 through 16965), we finalized an HCC-failure rate error estimation methodology that adjusts an issuer's enrollees' risk scores when the issuer's failure rate for a group of HCCs is statistically different from a national benchmark.¹⁰⁵ This methodology specifically calculates IVA-sampled enrollees' risk scores using their HCCs on EDGE and adjusts the HCC-portion of enrollees' risk scores based on audit results for issuers identified as outliers.¹⁰⁶ In the 2020 Payment Notice, we finalized a policy to incorporate RXCs beginning with 2018 benefit year HHS–RADV, and the 2021 Payment Notice finalized treating RXC validations in HHS–RADV as late-filed discrepancies, similar to demographic and enrollment errors.^{107 108 109} In

the population size, N , so that no more than 5 percent of the population is sampled. The FPC formula can be found in Section 2.6: Cochran, William G., *Sampling Techniques*, third edition, John Wiley & Sons, 1977.

⁹⁷ See the 2023 Benefit Year PPACA HHS–RADV Protocols. Section 7.2.1.8 (Alternate Sample Sizes) (June 4, 2024) available at: https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.

⁹⁸ See 79 FR 13756 through 13758.

⁹⁹ See *supra* note 92.

¹⁰⁰ In the initial years of HHS–RADV, we constrained the “10th stratum” of the IVA sample—that is, enrollees without HCCs selected for the IVA sample—to be one-third of the sampled IVA enrollees. In the 2020 Payment Notice, we finalized the extension of the Neyman allocation sampling methodology to the 10th stratum to improve sample precision and permit for a larger portion of the sample to be allocated to the HCC strata. See 84 FR 17494 through 17495.

¹⁰¹ See 78 FR 72332.

¹⁰² In the 2020 Payment Notice, we finalized piloting the incorporation of RXCs into the HHS–RADV process in the 2018 benefit year, which was the first year that RXCs were incorporated into the risk adjustment models. We also finalized incorporating RXC validation into HHS–RADV as a method of discovering materially incorrect EDGE server data submissions in a manner similar to how we address demographic and enrollment errors discovered during HHS–RADV beginning with the 2019 benefit year. See 84 FR 17501. We later extended the pilot years of incorporating RXCs into HHS–RADV to the 2019 and 2020 benefit years of HHS–RADV to increase consistency between the operations of these benefit years' HHS–RADV and facilitate the combination of the HHS–RADV adjustments for these benefit years as we transitioned to a concurrent application of HHS–RADV results. See 85 FR 77002 through 77005.

¹⁰³ In the Neyman allocation, risk score error is measured as the actual difference between enrollee's audit risk scores and EDGE risk scores and does not reflect the error rate derived in HHS–RADV error estimation.

¹⁰⁴ See 79 FR 13757.

¹⁰⁵ Failure rates are calculated based on the rate at which the IVA Entity (or the SVA Entity if these results are being used) was able to validate an issuer's HCCs during the HHS–RADV audit. Previously, individual HCCs were the unit of analysis for calculating failure rates. The 2023 Payment Notice finalized that coefficient estimation groups would be de-duplicated beginning with 2021 benefit year HHS–RADV, thereby altering the unit of analysis of failure rates to be de-duplicated Super HCCs, rather than individual HCCs. See 2023 Payment Notice, 87 FR 27208 at 27253–27256.

¹⁰⁶ See the HHS Notice of Benefit and Payment Parameters for 2019; Final Rule, 83 FR 16930 at 16961–16965 (April 17, 2018). Also see CMS. (2022, January 20). *Reissuing 2018 Benefit Year HHS Risk Adjustment Data Validation (RADV) Results Memo*. <https://www.cms.gov/files/document/reissuing-2018-hhs-radv-results.pdf>.

¹⁰⁷ See CMS. (2023). *Summary Report on Permanent Risk Adjustment Transfers for the 2022 Benefit Year*. (p. 8). <https://www.cms.gov/files/document/summary-report-permanent-risk-adjustment-transfers-2022-benefit-year.pdf>.

¹⁰⁸ As finalized in the 2020 Payment Notice, HHS does not use demographic and enrollment or RXC errors identified in HHS–RADV in its error rate calculations. Demographic and enrollment or RXC errors discovered during HHS–RADV are handled as late-filed discrepancies and may result in adjustments to the applicable benefit year RA transfer amount. See 84 FR 84 FR 17498 through 17503. Also see for example, Section 10.4 Validation of the 2023 Benefit Year PPACA HHS–RADV Protocols (June 4, 2024) available at https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.

¹⁰⁹ Only adult enrollees can have RXCs and the frequency of RXCs among adult enrollees is relatively low. HHS currently uses the enrollees with RXCs in the IVA sample for validating RXCs

addition, in the 2024 Payment Notice, to promote consistency between the EDGE Server Business Rules and the HHS–RADV Protocols, HHS discontinued the Lifelong Permanent Conditions List and the policy permitting the submission of non-EDGE claims in HHS–RADV beginning with the 2022 benefit year of HHS–RADV.¹¹⁰

After running the HHS–RADV program for several years, we now have several years of HHS–RADV data that could be evaluated and used to improve our IVA sampling methodology. When we finalized the IVA sampling methodology, we stated that we would reexamine our sampling assumptions and methodology over time using actual HHS–RADV enrollee data as it becomes available. As a result of these analyses and for the reasons explained in the sections below, we are proposing changes to the IVA sampling methodology.

2. Proposal To Exclude Enrollees Without HCCs From IVA Sampling

We first propose to modify IVA sampling to exclude stratum 10 enrollees, which would exclude enrollees that do not have HCCs nor RXCs and adult enrollees in strata 1 through 3 that have RXCs only, from IVA sampling beginning with benefit year 2025 HHS–RADV. The purpose of this proposal to remove these enrollees (“enrollees without HCCs”) is to better align our IVA sampling methodology with the error estimation methodology that was established in the 2019 Payment Notice, which calculates issuer risk score error rates and applies these error rates to the HCC-related portion of issuers’ plan liability risk scores,¹¹¹ and the HHS–RADV policies finalized in the 2024 Payment Notice to discontinue the Lifelong Permanent Conditions (LLPC) list and no longer allow non-EDGE claims beginning with the 2022 benefit year of HHS–RADV, which emphasize HHS–RADV’s focus on validating enrollee HCCs on EDGE.¹¹² After the finalization of these policies, to validate an HCC in HHS–RADV, a risk adjustment eligible diagnosis must be supported by appropriate medical record documentation and linked to a risk adjustment eligible claim accepted

by the issuer’s EDGE server. IVA and SVA entities can no longer rely on the LLPC list or non-EDGE claims to support abstracting diagnoses that are not linked to an accepted risk adjustment eligible claim on the issuer’s EDGE server. Under the current IVA sampling methodology, enrollees without HCCs are grouped into stratum 10 if they have no HCCs or RXCs, or into strata 1, 2, or 3 if they are adult enrollees with RXCs only (“RXC-only enrollees”). However, these enrollees do not have EDGE HCCs to validate during HHS–RADV. Moreover, they have HCC-associated EDGE risk scores equal to zero, so there is no risk score to adjust as a result of HHS–RADV. Therefore, this proposed policy to exclude enrollees without HCCs from IVA sampling ensures that issuers, IVA Entities, and SVA Entities (as applicable) are focusing resources on enrollees who have a more direct impact on Super HCC failure rates,¹¹³ issuers’ group failure rates, and issuers’ error rates in HHS–RADV.

Furthermore, RXC-only enrollees have been included in the HHS–RADV sampling of strata 1 through 3 to ensure an adequate number of enrollees with RXCs in issuers’ samples to complete HHS–RADV RXC validation.¹¹⁴ However, EDGE data from benefit years 2019 through 2022 shows that on average less than 12 percent of an issuer’s adult enrollee population with RXCs has no HCCs. Therefore, the vast majority of adult enrollees with RXCs also have HCCs and will therefore still be captured in strata 1 through 3 in the IVA sample and eligible for inclusion in the HHS–RADV RXC validation.¹¹⁵ In addition, removing RXC-only enrollees from IVA sampling aligns our IVA sampling methodology with the HHS–RADV error estimation methodology, which does not consider RXCs in error

estimation. We anticipate that this change will improve the precision of issuers’ group failure rates for any given sample size by ensuring that all enrollees from stratum 1, 2 or 3 have EDGE HCCs to validate in HHS–RADV that contribute to issuers’ error rate calculation. For these reasons, we propose to remove all enrollees without HCCs, which consists of stratum 10 enrollees and RXC-only enrollees, from IVA sampling. Under the proposal, enrollees without HCCs would be excluded from IVA sampling such that all 200 enrollees selected for IVA audit would have at least one EDGE HCC and would fall within strata 1 through 9.

3. Proposal To Remove the Finite Population Correction (FPC)

We propose to remove the FPC from the IVA sampling methodology such that, with the exclusion of enrollees without HCCs from IVA sampling, all issuers with at least 200 enrollees with HCCs in their enrollee population would have an IVA sample size of 200. Under this proposal, all issuers with fewer than 200 enrollees with HCCs would have an IVA sample size equal to their population of enrollees with HCCs. As previously explained, under the current IVA sampling methodology, issuers with between 51 and 3,999 enrollees in their total enrollee population are subject to the FPC and we calculate modified IVA sample sizes that are less than 200 enrollees using an FPC factor. Under the current approach, issuers with 50 or fewer enrollees have IVA sample sizes equal to their total enrollee population. We have found in recent years of HHS–RADV results that issuers with IVA sample sizes less than 200 enrollees are less likely to meet the 30 Super HCC constraint for outlier identification in a failure rate group.¹¹⁶ If an issuer fails to meet the 30 Super HCC constraint in all three failure rate groups, the issuer cannot be determined to be an outlier and then the risk scores of their sampled enrollees are not

in HHS–RADVs. See Section 7.2.1.9 RXC Sample Size of the 2023 Benefit Year PPACA HHS–RADV Protocols.

¹¹⁰ See 88 FR 25790 through 25796.

¹¹¹ See 83 FR 16930 at 16961 through 16965. Also see CMS. (2022, January 20). Reissuing 2018 Benefit Year HHS Risk Adjustment Data Validation (RADV) Results Memo. <https://www.cms.gov/files/document/reissuing-2018-hhs-radv-results.pdf>.

¹¹² For more detail on the 2024 Payment Notice policies regarding the LLPC list and non-EDGE claims, see 88 FR 25790 through 25796.

¹¹³ As previously mentioned, the 2023 Payment Notice altered the unit of analysis of failure rates to be de-duplicated Super HCCs, rather than individual HCCs. See 87 FR 27208 at 27253–27256. For more detail on how Super HCC failure rates are calculated, see Section 13.3.1.1.3 Calculate Super HCC Failure Rates and Categorize Super HCCs into Low, Medium, and High Failure Rate Groups of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4, 2024) available at https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.

¹¹⁴ As explained earlier in this preamble, HHS–RADV RXC validations are treated as late-filed discrepancies similar to demographic and enrollment errors. See 84 FR 17498 through 17503.

¹¹⁵ IVA Entities validate RXCs by reviewing claims, not medical records. See Section 10.4 Validation of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4, 2024) available at https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.

¹¹⁶ Under the outlier identification policy finalized in the 2021 Payment Notice, when HCCs were the unit of analysis of failure rates, an issuer could not be identified as an outlier in any failure rate group in which that issuer had fewer than 30 Super HCCs. See 85 FR 29196 through 29198. In the 2023 Payment Notice, when the unit of analysis of failure rates was altered to de-duplicated Super HCCs, we finalized 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. 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. See 87 FR 27254.

adjusted during error estimation.¹¹⁷ However, in our analysis of the proposal to exclude enrollees without HCCs from IVA sampling, we found that removing the FPC would give smaller issuers a better opportunity to increase the count of Super HCCs in their IVA sample because all enrollees sampled would have at least one HCC. Alternatively, retaining the FPC would continue to adjust these issuers' sample sizes downwards and greatly limit the number of Super HCCs in their IVA samples. By including more enrollees with HCCs in these smaller issuers' IVA samples, we would increase these issuers' probability of meeting the 30 Super HCC constraint and improve the precision of group failure rates during error estimation, as well as improve the precision of net risk score error as discussed below. In addition, for small issuers that meet the 30 Super HCC threshold, this proposal would further allow these issuers' risk scores to be appropriately adjusted if they are identified as outliers, and it would allow them to gain additional insights from a richer set of data elements reported in their HHS–RADV results to improve coding practices and EDGE data submission procedures (as applicable). For these reasons, we are proposing to remove the FPC beginning with 2025 benefit year HHS–RADV.

Under this proposal, issuers with less than 200 enrollees with HCCs would have all enrollees with HCCs in their IVA sample. The issuer-specific sample size would be equal to the sum of all of their enrollees with HCCs in strata 1 through 9 in their EDGE population subject to HHS–RADV.¹¹⁸ For issuers with at least 200 enrollees with HCCs, their IVA sample size would remain at 200 enrollees and HHS would continue to use the Neyman allocation to determine stratum sample sizes for enrollees with HCCs in strata 1 through 9.¹¹⁹

¹¹⁷ An issuer cannot be considered an outlier for a failure rate group in which the issuer has fewer than 30 de-duplicated EDGE Super HCCs but data from these issuers' failure rates is included in the calculation of national benchmarks. See 87 FR 27254 through 27255.

¹¹⁸ An issuer's EDGE population only consists of enrollees in their risk adjustment covered plans. See §§ 153.610(a) and 153.700(a). However, for example, issuers that are the sole issuer in a State market risk pool are not subject to risk adjustment data validation and therefore a sole issuer risk pool's enrollment would not be included in the population subject to HHS–RADV sampling. See 83 FR 16967.

¹¹⁹ If the Neyman-allocated sample size for a stratum exceeds the number of enrollees in that stratum, HHS uses the actual number of enrollees in that stratum in the issuer's population in place of the target Neyman-allocated sample size for that stratum. The Neyman optimal allocation method is then performed again using a positive or negative

Based on an analysis of historical HHS–RADV data, we estimate that issuers with less than 1,200 enrollees or approximately 10,000 billable member months statewide would be likely to have insufficient enrollees with HCCs in strata 1 through 9 to create an IVA sample size with 200 enrollees. These issuers would therefore have an IVA sample size equal to their EDGE population of enrollees who have HCCs. In the absence of the FPC, small issuers may have IVA sample sizes that are larger or smaller than their IVA sample size would have been if subjected to the FPC under the current methodology. However, any increase in IVA sample size would only be realized in the years that a smaller issuer is selected for HHS–RADV, which is approximately once every 3 years (barring any risk-based triggers that would warrant more frequent audits) under the materiality threshold exemption at § 153.630(g)(2).¹²⁰ In addition, we anticipate that the smaller issuers whose sample sizes would increase if the proposal to remove the FPC is finalized would also have an increase in Super HCC count in their IVA samples and group failure rate precision.¹²¹ As the set of data used to estimate an issuer's group failure rates increases, the precision of those sample estimates also increases, which is important as the issuer's outlier status depends on whether their group failure rates fall within the national benchmark confidence intervals. More specifically, we estimate that issuers receiving the FPC under the current methodology and whose IVA sample sizes would increase under the proposed methodology would see a 35 percent increase in Super HCC count in their IVA samples and a 26 percent increase in group failure rate precision on average across all three failure rate groups.¹²² We discuss the aggregate impact of all proposed IVA sampling policies, including the proposed removal of the FPC, on issuer burden in section 5 of this preamble and in the ICR section of this rule.

incremental value to adjust the target sample size, until the actual sample size derived by summing the Neyman output for strata 1 through 9 meets the target IVA sample size of 200.

¹²⁰ Issuers at or below the materiality threshold of 30,000 billable member months are only subject to random and targeted sampling every 3 years (barring any risk-based triggers based on experience that will warrant more frequent audit), and issuers below 500 billable member months statewide are exempt from HHS–RADV. See 88 FR 25788 through 25790.

¹²¹ As explained in section 5 of this preamble, this estimate is based on the combination of all proposed changes to the IVA sampling methodology.

¹²² *Ibid.*

4. Proposal To Source the IVA Sampling Neyman Allocation With HHS–RADV Data

We also propose to change the current IVA sampling methodology to replace the source of the Neyman allocation data with HHS–RADV data now that we have accumulated sufficient HHS–RADV data to test and evaluate using it for IVA sampling purposes. As explained earlier in this preamble, relying on the MA–RADV in the Neyman allocation requires a simplifying assumption that the standard deviation of risk score error within a risk-score subgrouping (low, medium, and high) is the same for the three age groups (adult, child, and infant). However, we have found that the variance of net risk score error differs considerably, both between the MA–RADV data and the available HHS–RADV data and across strata. Because the Neyman allocation calculates the optimal allocation to each stratum such that strata with greater variance in net risk score error are sampled more intensely and strata with less variance in net risk score error are sampled less intensely, this implies that the MA–RADV data yields considerably different sample sizes for each stratum than the HHS–RADV data. For example, our analysis found that while the median sample proportion of stratum 3 (Adult—High risk) enrollees is 39 percent using the MA–RADV data, this could decrease to 19 percent of the sample being composed of stratum 3 enrollees if HHS–RADV data were used.¹²³

For these reasons, beginning with 2025 benefit year HHS–RADV, we are proposing to no longer use MA–RADV data to calculate the standard deviation of risk score error ($S_{i,h}$) for use in the Neyman allocation and instead use a 3-year rolling-window of available HHS–RADV data. For a given benefit year of HHS–RADV, we would use the 3 most recent consecutive years of HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin as the source data for the Neyman allocation and would continue to combine enrollees in each stratum across all issuers to create a national variance of net risk score error to calculate the standard deviation of risk score error ($S_{i,h}$).¹²⁴ ¹²⁵ We considered

¹²³ As noted later in this preamble, this estimate reflects the combined impact of all proposed changes to the IVA sampling methodology.

¹²⁴ A new benefit year of HHS–RADV activities generally begins in the spring the year following the applicable benefit year when issuers can start selecting their IVA entity and IVA entities can start electing to participate in HHS–RADV for that benefit year. See, for example, the 2023 Benefit Year HHS–RADV Activities Timeline for the general

creating an issuer-specific variance of net risk score error given the proposed shift to using HHS–RADV data instead of MA–RADV data for IVA sampling purposes, but this would not be possible for all issuers as some issuers would not have 3 consecutive years of HHS–RADV data. For example, consistent with § 153.630(g)(2), an issuer that is at or below the materiality threshold for random and targeted sampling will only be sampled for HHS–RADV approximately once every 3 years and therefore would not have HHS–RADV data for the years that they are not sampled. These issuers would have to rely on fewer years of HHS–RADV data, meaning significantly fewer data points compared to other issuers that participated in all years, which could result in large variations in IVA sample stratum size and increased uncertainty in HHS–RADV. Therefore, we propose to continue calculating $S_{i,h}$ with a national variance of net risk score error, but to use a 3-year rolling window of HHS–RADV data rather than the MA–RADV data as the source data for the Neyman allocation. Under this proposed approach, we would re-calculate $S_{i,h}$ during each benefit year of HHS–RADV to use the 3 most recent consecutive years of HHS–RADV data with results that have been released before each benefit year's HHS–RADV activities begin. This proposed approach is consistent with our shift from the use of MarketScan® data to recalibrate the HHS risk adjustment models to instead use the 3 most recent consecutive years of enrollee-level EDGE data that are available at the time we incorporate the data in the draft recalibrated risk adjustment model coefficients published in the proposed rule for the applicable benefit year. In the context of HHS–RADV, a 3-year rolling window would capture population changes that occur over time while promoting stability in the estimates of $S_{i,h}$ in HHS–RADV year over year. For example, annual improvements in issuers' EDGE data submission could decrease differences between enrollees' HHS–RADV audit risk scores and EDGE risk scores, while annual changes in enrollment and EDGE enrollee risk profiles could change the enrollee stratification, such that the standard deviation of risk score error for each stratum changes over time. In addition, under our random and targeted

sampling policy for HHS–RADV, issuers below the materiality threshold participate in HHS–RADV approximately once every 3 years. Therefore, using a 3-year rolling window will help ensure the majority of issuers participating in HHS–RADV are reflected in the strata metrics.

In addition, the proposal to use HHS–RADV data rather than the MA–RADV data as the source data for the Neyman allocation would decrease burden on issuers and IVA Entities. More specifically, our analysis found that the MA–RADV data yields considerably different sample sizes for each stratum than the HHS–RADV data, and that using the HHS–RADV data rather than the MA–RADV data is likely to increase the proportion of the sample in the lower-risk groups and decrease the proportion of the sample in the high-risk group. This proposed change in sampled enrollees means that under this proposal, issuers would have relatively fewer medical records to review because of the increase in the proportion of sampled enrollees in the lower-risk strata and the decrease in the proportion of enrollees in higher-risk strata. To further explain, this decrease in estimated medical record review would occur because higher-risk enrollees tend to have relatively more medical records to review than lower-risk enrollees. Issuers spend time and resources on retrieving, reviewing, and submitting medical records and documentation for HHS–RADV, so the estimated decrease in the average number of medical records reviewed per enrollee in the IVA sample from replacing MA–RADV data with HHS–RADV data is expected to lead to a decrease in issuer burden. We further address the estimated aggregate burden impact of all IVA sampling policies proposed in this rule in section 5 of this preamble and the ICR section of this rule.

5. Impact of IVA Sampling Proposals

In preparation for proposing changes to HHS–RADV IVA sampling, HHS conducted several analyses to evaluate the impact of these proposals. Our analysis revealed that the proposed modifications to switch data for the Neyman allocation to use the 3 most recent consecutive years of HHS–RADV data with results that have been released before HHS–RADV activities begin for the given benefit year, combined with the proposal to remove enrollees without HCCs from IVA sampling, and to remove the FPC would improve our ability to reach the 10 percent sampling precision target for net risk score error for a greater proportion of issuers in

HHS–RADV.¹²⁶ More specifically, when we evaluated the proposed IVA sampling methodology reflecting the changes outlined in this rule, which excludes enrollees without HCCs, removes the FPC, and replaces the MA–RADV data with available HHS–RADV data as the source data for the Neyman allocation, using HHS–RADV data from the 2022 benefit year, we found that more than 99 percent of issuers met the 10 percent sampling precision target for net risk score error at a two-sided 95 percent confidence level.

Our analysis also focused on the impact of the proposed policies on group failure rate precision. Previously, in the 2019 HHS–RADV White Paper, we evaluated how precise the current IVA sampling methodology was in measuring group failure rates and estimated that approximately 60 percent of issuers with a sample size of 200 enrollees met 10 percent group failure rate precision in all three HCC groups.¹²⁷ In comparison, under the proposed changes to the IVA sampling methodology in this rule, our analysis found that approximately 91 percent of all issuers in HHS–RADV would meet the 10 percent group failure rate precision in all three Super HCC groups. Moreover, approximately 87 percent of issuers with IVA sample sizes less than 200 would also meet the 10 percent group failure rate precision target in all three Super HCC groups.

In addition, we anticipate that the proposed changes to the IVA sampling methodology in this rule would result in an overall decrease in the number of medical records reviewed by IVA Entities. Issuers spend time and resources on retrieving, reviewing, and submitting medical records and documentation for IVA Entities to review, so the estimated decrease in medical records reviewed is expected to lead to a decrease in issuer burden. Although every enrollee sampled for the IVA would have HCCs, the proportion of enrollees sampled from strata 1 through 9 would change such that enrollees with more medical records are sampled less intensely due to the replacement of MA–RADV data with HHS–RADV data for the Neyman allocation. As mentioned earlier in this preamble, the median sample proportion of high-risk adult enrollees,

¹²⁶ The precision of net risk score error reflects the ability of the IVA sampling methodology to consistently estimate the percent difference between enrollees' audit risk scores and EDGE risk scores. See Section 1. IVA Sampling Background of this preamble for more detail on how the 10 percent sampling target was derived.

¹²⁷ See Section 2.3.6 Precision of Current Sample Sizes of the 2019 HHS–RADV White Paper.

structure of the HHS–RADV timeline. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.

¹²⁵ As an example, if finalized as proposed, we would use HHS–RADV data from benefit years 2021, 2022 and 2023 for the Neyman allocation for benefit year 2025 HHS–RADV.

who have more medical records to review on average, could decrease from 39 percent of the sample to 19 percent under the updated IVA sampling methodology reflecting the proposed changes in this rule. We describe our estimates of the proposed methodology on issuer burden in more detail in the ICR section of this rule.

We also analyzed the impact of replacing the source data for the Neyman allocation with HHS–RADV data while continuing to include enrollees without HCCs in IVA sampling and retaining the FPC. However, this would result in sampling a greater proportion of enrollees without HCCs, who do not have risk scores to adjust when calculating issuers' error rates during HHS–RADV. In addition, keeping the FPC while excluding enrollees without HCCs from IVA sampling and replacing the source data for the Neyman allocation with available HHS–RADV data would lead to a dramatic increase in the number of issuers subject to the FPC and therefore decrease the total count of Super HCCs in issuers' IVA samples. For example, we estimate that the average Super HCC count for issuers currently subject to the FPC would decrease by 26 percent by keeping the FPC, which would increase the proportion of issuers that fail to meet the 30 Super HCC constraint in HHS–RADV. In contrast, removing the FPC would increase the average Super HCC count for these same issuers by 30 percent, which would improve these issuers' probability of meeting the 30 Super HCC constraint. Overall, we found that making all proposed modifications in unison led to the greatest improvements in sampling precision and group failure rate precision across all issuers and a decrease in aggregate issuer burden.

As explained above, removing enrollees without HCCs and the FPC, and updating the source of the IVA sampling Neyman allocation data to use HHS–RADV data, leads to an IVA sample that improves sampling precision while decreasing burden on issuers and IVA Entities on average. Therefore, we are proposing to exclude enrollees without HCCs from IVA sampling such that each enrollee in an issuer's IVA sample must have at least one HCC, remove the FPC, and discontinue use of MA–RADV data as the source for the Neyman allocation calculation and begin using the 3 most recent consecutive years of HHS–RADV data with results that have been released before HHS–RADV activities for the benefit year begin.

We solicit comments on these proposed changes to the IVA sampling

methodology, the estimated impact of the changes, the timing of the implementation of the IVA sampling changes and feedback on whether there are other IVA sample changes that should be considered.

We seek comment on these proposals.

a. b. Second Validation Audit (SVA) Pairwise Means Test (§ 153.630(c))

To improve the sensitivity of the SVA pairwise means test, we propose to modify the test, which currently uses a paired sample t-test methodology, to use a bootstrapping methodology, and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV.¹²⁸

In the 2014 Payment Notice (78 FR 15437), we established that an SVA will be conducted by an entity retained by HHS to verify the accuracy of the findings of the IVA. Consistent with § 153.630(c), HHS selects a subsample of the risk adjustment data validated by the IVA for the SVA. The HHS–RADV SVA sampling methodology was originally developed in the 2015 Payment Notice (79 FR 13761) and is designed to identify statistical differences between the IVA and SVA results. To do this, the SVA Entity currently starts by reviewing the medical records of an initial subsample of 12 enrollees from the IVA sample. The SVA subsample expands to include 24, 50, and 100 enrollees in the IVA sample¹²⁹ when statistically significant

differences between the IVA and SVA results are identified at the sample-level under review. The SVA Entity identifies statistically significant differences in subsampled enrollees' IVA and SVA results using a paired sample t-test, which currently uses the t-distribution to build a 95 percent confidence interval around the difference between enrollee's IVA and SVA risk scores. If this confidence interval includes zero, then a statistically significant difference is not detected, and the issuer's IVA results are used in error estimation. If this confidence interval does not include zero, then there is a pairwise means testing failure at that subsample level, which requires SVA expansion to the next subsample level. As finalized in the 2020 Payment Notice (84 FR 17498), if the issuer fails the pairwise means test at SVA 100, a precision analysis is performed to determine whether the SVA audit results from the SVA 100 subsample can be used in error estimation or if the SVA sample needs to expand to the full IVA sample of 200 enrollees¹³⁰ with the SVA 200 results used in error estimation.¹³¹

The pairwise means testing procedure promotes the integrity and effectiveness of HHS–RADV by ensuring that error estimation and the HHS–RADV adjustments to risk scores are based on the most reliable medical coder review data possible. As such, it is important that the pairwise means testing procedure can detect when issuers' IVA results significantly differ from their SVA results at the initial sample size. Based on our experience operating HHS–RADV for the past several benefit years, we have reassessed the sensitivity of our pairwise means testing procedure, meaning the ability of the statistical test to identify statistically significant differences between IVA and

¹²⁸ Activities related to the 2024 benefit year of HHS–RADV will generally begin in March 2025, when issuers can start selecting their IVA entity, and IVA entities can start electing to participate in HHS–RADV for the 2024 benefit year. The SVA typically starts the January 2 years after the applicable benefit year (January 2026 for the 2024 benefit year of HHS–RADV) once issuers' IVA results have been submitted. See HHS, (2024, March 27). *2023 Benefit Year HHS–RADV Activities Timeline for the general structure of the HHS–RADV timeline*. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf. These changes to the SVA framework do not impact or change issuer or IVA Entity obligations or requirements; therefore, we are proposing to implement the proposed changes to the SVA pairwise means test starting with the 2024 benefit year HHS–RADV.

¹²⁹ A standard HHS–RADV IVA sample size is 200 enrollees, and it applies to the majority of issuers of risk adjustment covered plans. CMS calculates a smaller IVA sample sizes for issuers with smaller populations by using a Finite Population Correction (FPC) factor. All issuers are subject to the same SVA subsample sizes, but the maximum SVA subsample for pairwise testing is one half of the issuer's IVA sample size. As discussed in section II.B.5.a, we are proposing changes to the IVA sampling methodology that would exclude enrollees without HCCs from IVA sampling and remove the FPC factor such that all IVA samples will consist of 200 enrollees with HCCs or the issuer's total population of enrollees with HCCs if they have less than 200 enrollees with HCCs beginning with the 2025 benefit year of HHS–

RADV. Under this policy, the SVA subsample size expansion for issuers with less than 200 enrollees with HCCs would continue to follow the standard SVA subsample sizes with a maximum SVA subsample for pairwise testing equal to one half of the issuer's IVA sample size. If the issuer fails at the maximum SVA subsample size for pairwise testing, a precision analysis is performed to determine whether the SVA audit results from that maximum SVA subsample size can be used in error estimation or if the SVA sample needs to expand to the full IVA sample.

¹³⁰ Id.

¹³¹ See Section 11.6.2 Pairwise Means Test to Determine Accepted Results (IVA vs. SVA) of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4, 2024) available at https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf. For issuers with the FPC, if there is insufficient agreement between IVA and SVA findings at the maximum total SVA subsample for pairwise testing, a precision analysis is performed to determine whether it is necessary to expand the SVA sample to the full IVA sample for error estimation.

SVA risk scores when they exist, to see whether changes are needed. Based on our reassessment, we believe that the pairwise means testing procedure should be modified to use a 90 percent bootstrapped confidence interval, rather than a t-test with a 95 percent confidence interval, and to increase the initial SVA subsample level from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV to improve the detection of differences between IVA and SVA results.

To assess our current pairwise means testing procedure, we conducted a power analysis to investigate its sensitivity in detecting population-level differences. The analysis focused on “false negatives,” a detection error that occurs when there are significant differences between IVA and SVA results, but the statistical test does not identify a statistically significant difference between IVA and SVA enrollee risk scores. We are concerned about “false negatives” and therefore focused on them because they result in an atypical issuer passing the pairwise means test and the conclusion of the SVA review without further investigation at a higher subsample level. Our power analysis found that when using a subsample size of 12 enrollees the current paired sample t-test using a 95 percent confidence interval results in a false negative rate of over the target false negative rate of 20 percent at any of the simulated effect sizes.^{132 133}

As part of our examination of ways to address our concerns about false negatives in the current pairwise means testing procedure, we expanded our power analysis by investigating the use of a bootstrapping methodology as an alternative pairwise means testing procedure to identify statistically significant differences between IVA and SVA risk scores. A bootstrapping approach is a useful technique to construct confidence intervals when the underlying distribution is unknown, when sample size may be too small to assume a normal sampling distribution, or when no formula exists to describe the sampling distribution of a particular

point estimate.¹³⁴ When conducting the SVA pairwise means test, we do not know each issuer’s population distribution of IVA and SVA risk score differences because our sample is limited to the applicable SVA subsample level. However, by simulating bootstrapped samples based on observed IVA and SVA risk score differences at a given SVA subsample level, we can build each issuer’s sampling distribution and calculate standard errors and confidence intervals to improve the sensitivity of the test used to identify statistically significant differences between IVA and SVA results.

In particular, at a given SVA subsample level, the proposed pairwise bootstrapping methodology would perform 10,000 iterations of resampling with replacement from the enrollees in the issuer’s SVA subsample at that level. The average difference between enrollees’ IVA and SVA risk scores would be calculated for each resample to build an issuer-specific confidence interval for statistical testing of enrollee’s IVA and SVA risk scores. Like the current pairwise means test, if the bootstrapped confidence interval contains zero, the bootstrapping procedure would show non-significant differences between IVA and SVA risk scores, and the issuer would pass pairwise means testing at that SVA subsample level and IVA results would be used in error estimation. If the bootstrapped confidence interval does not include zero, the differences between IVA and SVA risk scores identified would be statistically significant, and the issuer would fail pairwise means testing at that SVA subsample level. In these circumstances, the SVA subsample would be expanded and the pairwise means test conducted at that new SVA subsample level. If the issuer continues to fail the pairwise means test at the SVA 100-level, a precision analysis would be performed to determine whether the SVA audit results from the SVA 100 subsample can be used in error estimation or if the SVA sample needs to expand to the full IVA sample of 200 enrollees with the SVA 200 results used in error estimation.¹³⁵

We tested the bootstrapping methodology using a variety of confidence levels and found that using a bootstrapped confidence interval of 90 percent, rather than the current paired t-test with a 95 percent confidence interval, improves the pairwise means testing procedure’s sensitivity and ability to detect when issuers’ IVA results differ substantially from their SVA results. The proposed bootstrapping methodology with a 95 percent confidence interval achieves a lower rate of false negatives at smaller sample sizes for any given effect size compared to the current paired t-test methodology. Moreover, decreasing the size of the confidence interval from 95 percent to 90 percent under the bootstrapping methodology decreases the sample size required to achieve a targeted false negative rate of 20 percent, and therefore increases the probability of detecting significant differences when they exist. On the other hand, decreasing the confidence interval from 95 percent to 90 percent implies that the rate of false positives, or the rate at which an enrollee population with no major differences between IVA and SVA results would return a statistically significant finding at a given sample size, would increase from 5 percent to 10 percent. The reasonable increased false positive rate, in combination with the increased sensitivity of the bootstrapping methodology, would result in more issuers being expanded to larger SVA sample sizes during pairwise means testing. However, we believe that the increased false positive rate is necessary and appropriate to achieve an acceptable rate of false negatives and ensure that reliable audit results are used in error estimation. We also believe that in comparison to false negatives, false positives can be addressed through the expansion of the sample size and therefore, pose less of a concern than false negatives, which cannot be corrected for since a false negative would end the SVA review at the lower sample size. Therefore, we believe that the proposed changes to improve the sensitivity of the SVA pairwise means test achieve the right balance between false negatives and false positives.

Because the false negative rate decreases as sample size increases, the power analysis also showed the advantages of increasing the initial SVA subsample size beyond 12 enrollees. Specifically, under the proposed

¹³² These effect sizes use the Cohen’s D effect size measure and correspond to the recommended interpretations of a small, medium, and large effect size. See Cohen, Jacob (1988). *Statistical Power Analysis for the Behavioral Sciences*. Routledge. ISBN 978–1–134–74270–7. pp 25–27.

¹³³ The conventional minimum power desired for most research settings is 80 percent, which implies a false negative rate of 20 percent. See Cohen, Jacob (1988). *Statistical Power Analysis for the Behavioral Sciences*. Routledge. ISBN 978–1–134–74270–7. pp. 25–27.

¹³⁴ We use bootstrapping techniques in other parts of HHS–RADV error estimation, such as for calculating error rate precision. See Section 11.6.3 Calculating Error Rate Precision of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4, 2024) available at https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.

¹³⁵ See Section 11.6.2 Pairwise Means Test to Determine Accepted Results (IVA vs. SVA) of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4,

2024) available at https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.

bootstrapping methodology using a 90 percent confidence interval, we could achieve a false negative rate of 20 percent at medium and large effect sizes by increasing the initial SVA subsample size to 24 enrollees. We also recognize these proposed changes to increase the initial review sample size and adopt the proposed bootstrapping methodology using a 90 percent confidence interval, would likely increase the scale of HHS' SVA review and therefore increase the costs to conduct the SVA. While the increase in the scale of HHS' SVA review would increase costs, as discussed in the regulatory alternatives section of this rule, we do not anticipate the proposed changes to improve the sensitivity of the SVA pairwise means test will significantly impact the timeline to conduct error estimation. As in any year of HHS–RADV, the timeline for conducting error estimation may be adjusted in response to the volume of SVA discrepancies submitted because the SVA discrepancy window occurs prior to the release of error rate results. Ultimately, we believe that these proposed changes to improve the sensitivity of the SVA pairwise means test are necessary and appropriate to address the identified concerns regarding “false negatives” and to promote the integrity of HHS–RADV. Therefore, we are proposing to modify the pairwise means test to use a bootstrapping methodology using a 90 percent confidence interval and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV.

We seek comment on the proposal to modify the SVA pairwise means testing procedure to use a bootstrapped 90 percent confidence interval and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV.

b. c. HHS–RADV Materiality Threshold for Rerunning HHS–RADV Results (§ 156.1220(a)(2))

We propose to amend § 156.1220(a) to codify a new, second materiality threshold for HHS–RADV appeals, hereafter referred to as the materiality threshold for rerunning HHS–RADV results.¹³⁶ This proposal would codify a

¹³⁶ For purposes of this proposal, rerunning HHS–RADV results involves recalculating all national program benchmarks and issuers' error rate results, reissuing issuers' error rate results, conducting discrepancy reporting and appeal windows for the reissued results, applying the reissued error rates to the applicable benefit year's State transfers, and invoicing, collecting, and distributing any additional changes to the HHS–RADV adjustments to State transfers.

standard for when HHS would take action to rerun HHS–RADV results and adjust HHS–RADV adjustments to State transfers in response to a successful appeal. We propose to amend § 156.1220 to add a new paragraph (a)(2)(i) to provide that HHS would rerun HHS–RADV results in response to an appeal when the impact to the issuer who submitted the appeal (that is, the filer's) HHS–RADV adjustments to State transfers is greater than or equal to \$10,000. This proposal is further discussed in part 156 (§ 156.1220) below.

C. Part 155—Exchange Establishment Standards and Other Related Standards

1. Solicitation of Comments—Navigator, Non-Navigator Assistance Personnel, and Certified Application Counselor Program Standards (§§ 155.210, 155.215, and 155.225)

We are soliciting comment regarding how assisters who perform their assister duties in a hospital and hospital system may, within the bounds of the statute, refer consumers to programs designed to reduce medical debt.

Sections 1311(d)(4)(K) and 1311(i) of the ACA direct all Exchanges to establish a Navigator program. Navigator duties and requirements for all Exchanges are set forth in section 1311(i) of the ACA and § 155.210. Section 1321(a)(1) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA, for, among other things, the establishment and operation of Exchanges. Pursuant to section 1321(a)(1) of the ACA, the Secretary issued § 155.205(d) and (e), which requires Exchanges to perform certain consumer service functions in addition to the Navigator program. To satisfy these requirements, Exchanges may establish a non-Navigator assistance personnel program, as the FFEs have done, and must have a Certified Application Counselor (CAC) program. Existing regulations outlining duties and required activities for Navigators (§ 155.210(e)), non-Navigator assistance personnel (§ 155.215, through the cross-reference to § 155.210(e)), and CACs (§ 155.225(c)) were initially finalized in the 2015 Market Standards final rule (79 FR 30240).

The purpose of these assister programs is to ensure there are various ways consumers can receive help as they apply for and enroll in coverage through the Exchanges. In particular, Navigators (among other duties) help consumers make informed decisions during the health coverage selection process in a fair and impartial way,

provide assistance in culturally and linguistically appropriate ways,¹³⁷ and assist consumers with certain post-enrollment activities such as understanding the process of filing eligibility appeals as well as basic concepts and rights related to health coverage and how to use it. Non-Navigator assistance personnel conduct direct assister-to-consumer outreach alongside Navigators to provide consumers with information in a fair and impartial way, which includes providing assistance with submitting the eligibility application, clarifying distinctions among health coverage options and helping consumers make informed decisions during the health coverage selection process. CACs provide information to consumers about the full range of QHP options and insurance affordability programs for which they are eligible, assist consumers with applying for coverage in a QHP, and help facilitate enrollment of eligible individuals in QHPs and insurance affordability programs.

The Consumer Financial Protection Bureau estimates that \$88 billion of outstanding medical bills are currently in collections, affecting one in five Americans.¹³⁸ High levels of medical debt, and their impact on consumer credit scores, have led to cascading negative effects for consumers and their families such as reduced credit, greater risk of personal bankruptcy, delays in seeking necessary health care services, and housing insecurity. These challenges also disproportionately fall on more vulnerable or underserved consumers, including young adults, veterans, people with low incomes, and Black and Hispanic populations.¹³⁹ Assister programs located within hospitals or as part of hospital systems could help ensure that the consumers they serve are aware of the financial assistance programs those entities provide. This can ultimately help to ensure the financial well-being of consumers as they seek health care.

We are interested in receiving comments about what we may do within the scope of our authority as it

¹³⁷ Navigators receiving federal financial assistance are required to comply with the Section 1557's requirements on access for individuals with limited English proficiency, see CFR 45 § 92.201: <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-92>.

¹³⁸ Consumer Financial Protection Bureau. (n.d.) *Medical Debt*. <https://www.consumerfinance.gov/rules-policy/medical-debt/>.

¹³⁹ See for example, Levey, N. (2022, June 16). *100 Million People in America Are Saddled With Health Care Debt—KFF Health News*. KFF Health News. <https://kffhealthnews.org/news/article/diagnosis-debt-investigation-100-million-americans-hidden-medical-debt/>.

relates to Navigators and other assisters to help connect consumers to financial assistance programs within hospitals, hospital systems, and their communities.

2. 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. Engaging in Compliance Reviews and Taking Enforcement Actions Against Lead Agents for Insurance Agencies

We address our authority under § 155.220 to reach misconduct or noncompliance occurring at an agency-level,¹⁴⁰ by undertaking compliance reviews of and enforcement action against an insurance agency's ("agency's") "lead agent(s)," ¹⁴¹ and discuss how we intend to utilize this authority to hold agencies accountable for misconduct or noncompliance with applicable HHS Exchange standards and requirements under § 155.220.

Section 155.220 currently applies to an agent, broker, or web-broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for APTC and CSRs for coverage offered through an Exchange. "Web-broker" is defined in § 155.20 as an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchange as described in § 155.220(c)(3) or § 155.221.¹⁴² Section 155.20 defines "agent or broker" as a person or entity licensed by the State as an agent, broker or insurance producer.

We are not proposing amendments to our existing regulations to codify our

approach to hold agencies accountable for misconduct or noncompliance with applicable standards and requirements in § 155.220 because they can reasonably be interpreted to apply to agencies that are involved in Exchange enrollment transactions, since agencies are entities licensed by the State as an agent, broker, or insurance producer. As such, agencies would fall under the current definitions of "agent or broker" and "web-broker" in § 155.20.

Many FFE or SBE-FP enrollments are conducted by individual agents, brokers, or web-brokers who work for an agency and provide the agency's business NPN on the consumer's eligibility application submitted to an FFE or SBE-FP. An agency's business NPN can be included on a consumer's eligibility application when individual agents, brokers, or web-brokers who work at the agency are assisting consumers with enrolling in QHPs or applying for APTC and CSRs and the person associated with the agency's business NPN completes the FFE registration process, takes the required training, and signs the applicable Exchange Agreements ¹⁴³ with CMS. These are annual requirements that need to be met anew each plan year.¹⁴⁴ In addition, Exchange enrollees or applicants may provide their consent to enroll in a QHP offered through an Exchange to an entire agency instead of, or in addition to, an individual agent, broker, or web-broker. This provides more flexibility, both for agents, brokers, web-brokers, and enrollees and applicants, by helping ensure consumers are able to reach someone who is authorized to assist them if they have questions or wish to make a plan change in the future, which also helps improve the consumer's experience.

The listing of a business NPN on the consumer's eligibility application or enrollment transaction submitted to an

FFE or SBE-FP underscores the importance of holding agencies accountable for complying with the same standards and requirements as individual agents, brokers, or web-brokers. Applications and enrollments submitted to an FFE or SBE-FP that include a business NPN can impact Exchange operations, Exchange information technology systems, and Exchange enrollees or applicants, similar to situations where an individual agent, broker, or web-broker who does not work for an agency submits an application or enrollment to an FFE or SBE-FP. As such, we are addressing our authority to reach misconduct or noncompliance occurring at an agency-level and discussing how we intend to utilize this existing authority to hold agencies accountable for agency-level misconduct or noncompliance.

Section 1312(e) of the ACA directs the Secretary to establish procedures under which a State may permit agents and brokers to enroll individuals and employers in QHPs through an Exchange and to assist individuals in applying for financial assistance for QHPs sold through an Exchange. In addition, section 1313(a)(5)(A) of the ACA directs the Secretary to provide for the efficient and nondiscriminatory administration of Exchange activities and to implement any measure or procedure the Secretary determines is appropriate to reduce fraud and abuse. Section 1321(a) of the ACA provides broad authority to the Secretary to establish standards and issue regulations to implement the statutory requirements related to Exchanges, QHPs, and other components of title I of the ACA, which includes sections 1312 and 1313 of the ACA, and this statutory provision also provides the Secretary authority to implement other requirements as the Secretary determines appropriate. In prior rulemakings, we used these authorities to adopt § 155.220, which establishes standards and requirements applicable to agents, brokers, and web-brokers assisting individuals, employers, or employees with enrollment in QHPs offered through an Exchange.

We propose to utilize the same authorities against lead agents ¹⁴⁵ that are currently used to engage in compliance reviews of and enforcement actions against agents, brokers, and web-brokers. This includes the agent, broker, and web-broker compliance reviews and enforcement actions under § 155.220, which allow HHS to periodically monitor and audit an agent, broker, or

¹⁴⁰ For purposes of this proposal, "agency-level" misconduct or noncompliance refers to misconduct or noncompliance with HHS Exchange standards and requirements under § 155.220 associated with an eligibility application or enrollment transaction that lists an agency's NPN or that the agency was involved in or facilitated the submission of, or misconduct or noncompliance with HHS Exchange standards and requirements under § 155.220 that involves the agency's lead agent(s) or that the agency endorsed or is otherwise involved in.

¹⁴¹ The term "lead agent" refers to any person who registers and/or maintains a business with a State and/or any person who registers a business National Producer Number (NPN) with the Exchange, who typically is an executive or person with a leadership role within an agency.

¹⁴² The term also includes an agent or broker direct enrollment technology provider. See § 155.20.

¹⁴³ There are currently three Exchange Agreements with CMS that extend to agents or brokers assisting consumers in the FFEs and SBE-FPs: (1) the Agent Broker General Agreement for Individual Market FFEs and SBE-FPs, (2) the Agent Broker Privacy and Security Agreement for Individual Market FFEs and SBE-FPs, and (3) the Agent Broker SHOP Privacy and Security Agreement. Web-brokers assisting consumers in the FFEs and SBE-FPs are required to sign the Web-broker General Agreement, and web-brokers who are primary Enhanced Direct Enrollment (EDE) entities that assist consumers in the FFEs and SBE-FPs are required to sign the EDE Business Agreement and the Interconnection Security Agreement.

¹⁴⁴ In addition, each individual agent or broker who wishes to include the business entity NPN on Exchange eligibility applications must also complete the annual registration process, take the required trainings, and sign the applicable Exchange Agreements with CMS for the applicable plan year using their individual NPN.

¹⁴⁵ See supra note 138.

web-broker to assess their compliance with the applicable requirements of § 155.220.¹⁴⁶ Section 155.220(g) sets forth standards for suspension and termination of the agent's, broker's, or web-broker's Exchange Agreements for cause, which ends their participation in the FFEs.¹⁴⁷ These enforcement actions may be taken in three situations: (1) for specific findings or patterns of noncompliance,¹⁴⁸ (2) failure to maintain proper licensure in all States where the agent, broker, or web-broker is assisting consumers,¹⁴⁹ and (3) for engaging in fraud or abusive conduct.¹⁵⁰ Section 155.220(k) sets forth penalties other than suspension or termination of the agent's, broker's, or web-broker's Exchange Agreements for the current plan year. If an agent, broker, or web-broker fails to comply with the requirements of § 155.220, HHS may deny an agent, broker, or web-broker the right to enter into Exchange Agreements in future years¹⁵¹ or impose a civil money penalty as described in § 155.285.¹⁵² Lastly, HHS may immediately impose a system suspension against an agent or broker if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems.¹⁵³ System suspensions differ from Exchange Agreement suspensions because they prevent the agent or broker from utilizing Direct Enrollment (DE) platforms to enroll consumers but do not prevent them from enrolling consumers using *HealthCare.gov* or the Marketplace Call Center because they are still considered registered with the FFE.

Consistent with § 155.220(l), the FFE standards and requirements in § 155.220

also apply to agents, brokers, and web-brokers that assist with or facilitate enrollment in States with SBE-FPs.¹⁵⁴ Under the approach described in this preamble, leveraging the existing definitions of "agent or broker" and "web-broker" in § 155.20, we would also extend our authority to engage in compliance reviews and take enforcement actions to reach lead agents in both FFE and SBE-FP States who may be engaged in misconduct or are noncompliant with applicable standards and requirements in § 155.220. We believe this would better align our oversight and enforcement approach with how States regulate agencies.

The NPN is a unique identifier for an agent, broker, web-broker, or agency that the National Association of Insurance Commissioners assigns during the State licensing application process. The NPN can be recorded as part of the consumer's Exchange eligibility application and is used to track which individual agents, brokers, or web-brokers and agencies assisted Exchange consumers. QHP issuers use the NPN to identify the agent, broker, web-broker, or agency for compensation purposes. Either the NPN of the individual agent, broker, or web-broker assisting the consumer, or the business NPN of the agency, may be listed on the consumer's eligibility application submitted to an FFE or SBE-FP. In the most recent Open Enrollment survey, approximately 4 percent of respondents attested to using a business NPN for all their enrollments.¹⁵⁵ That means at least 640,000 enrollments¹⁵⁶ contained an NPN that did not belong to an individual agent, broker, or web-broker. The NPN, when provided, is a key identifying element in any compliance review under § 155.220(c)(5) or enforcement action by HHS under § 155.220(c)(4)(ii), (g)(1), (g)(3)(ii), (g)(5), (k)(1)(i), (k)(1)(ii), and (k)(3).

Under the approach described in this preamble, when information suggests there is agency-level misconduct or noncompliance, an investigation or compliance review would occur, and enforcement action may be taken. Any such compliance review, or enforcement action would be directed at the lead agent(s) and any other agent, broker, or web-broker who is discovered to be involved in the misconduct or

noncompliant activity. When the misconduct or noncompliant activity is occurring at the agency-level, we believe it is appropriate for the lead agents to be subject to the compliance review, or enforcement action, in addition to the agents, brokers, or web-brokers working at or for an agency that may have been involved in the misconduct or noncompliant activity, as those lead agents are the individuals responsible for directing and/or overseeing their employees' and contractors' behavior and activity. Engaging in compliance reviews and taking enforcement actions against lead agents in these circumstances would ensure that the individuals who are directing and/or overseeing the misconduct or noncompliance are held accountable.

The first step (of two) we would take in determining if we would engage in a compliance review or enforcement action against the lead agents would be to determine if there appears to be agency-level endorsement of, or agency-level involvement in,¹⁵⁷ the misconduct or noncompliant behavior or activities of the agency's employees, contractors, or other agents, brokers, or web-brokers. Endorsement would involve the agency supporting or approving, either explicitly or implicitly, the relevant misconduct or noncompliant behavior or activities. Explicit endorsement may include written directives to agents, brokers, or web-brokers to engage in certain impermissible behavior, such as to submit eligibility applications without obtaining and documenting review and confirmation by the consumer (or their authorized representative) of the accuracy of the eligibility application information, as required by § 155.200(j)(2)(ii). Implicit endorsement may involve an agency continuing to employ an agent, broker, or web-broker whom they know has submitted consumer eligibility applications without first obtaining and documenting consumer consent, as required by § 155.200(j)(2)(iii).

Agency-level endorsement would indicate the misconduct or noncompliant behavior or activities are not random, isolated occurrences undertaken by a singular agent, broker, or web-broker and that the agency, and its lead agent(s), may be complicit in such misconduct or noncompliant behavior or activities. Determining if there is agency-level endorsement or involvement would involve review of

¹⁴⁶ 45 CFR 155.220(c)(5).

¹⁴⁷ We notify State Departments of Insurance when we suspend or terminate the Exchange Agreement(s) of an agent, broker, or web-broker under § 155.220(g), per § 155.220(g)(6). We also maintain and publish the Agent and Broker Federally-facilitated Marketplace (FFM) Registration Termination List, which allows QHP issuers, consumers, and other interested parties to search for NPNs associated with agents, brokers, and web-brokers whose Exchange Agreement(s) have been terminated or suspended. See <https://data.healthcare.gov/ab-suspension-and-termination-list>.

¹⁴⁸ 45 CFR 155.220(g)(1).

¹⁴⁹ 45 CFR 155.220(g)(3)(ii).

¹⁵⁰ 45 CFR 155.220(g)(5).

¹⁵¹ 45 CFR 155.220(k)(1)(i).

¹⁵² 45 CFR 155.220(k)(1)(ii).

¹⁵³ 45 CFR 155.220(k)(3). HHS also authority to temporarily suspend the ability of a web-broker to make its non-Exchange website available to transact information with HHS, if HHS discovers a security and privacy incident or breach, for the period in which HHS begins to conduct an investigation and until the incident or breach is remedied to HHS' satisfaction. See 45 CFR 155.220(c)(4)(iii).

¹⁵⁴ This includes the extension of the HHS authorities under § 155.220 to engage in compliance reviews and take enforcement actions with respect to misconduct or noncompliance by agents, brokers, or web-brokers in States with SBE-FPs.

¹⁵⁵ Open Enrollment Survey, conducted between January 29, 2024, and February 14, 2024.

¹⁵⁶ Based on the PY 2024 enrollment total of 16 million consumers.

¹⁵⁷ Examples, but not an exhaustive list, of agency-level involvement could be agency-level directives or materials provided to employees telling them to engage in such activity or the agency not stopping noncompliant behavior when the agency is aware of it.

several sources of information, some of which we discuss below. One source of information is data metrics involving lead agents, such as compliance data, to determine if we have received complaints directed towards an individual who is a lead agent for the agency in question. An agency whose lead agent is named in complaints, especially for unauthorized enrollments or other potentially fraudulent or noncompliant activity, could trigger a compliance review or enforcement action against the lead agent(s) at the agency, as it could indicate agency endorsement of or involvement in misconduct or noncompliant behavior or activities, including inaction by the agency to try to curb the misconduct or noncompliant behavior or activities. We would also look to see if complaints against a lead agent for an agency are similar to complaints received against the agency's other agents, brokers, or web-broker,¹⁵⁸ which could indicate agency-level endorsement or involvement in the misconduct or noncompliant behavior or activities.

Additionally, we would utilize system monitoring to identify potential misconduct or noncompliant behavior or activities. For example, we currently engage, and would continue to engage, in system monitoring by analyzing person searches on approved Classic DE and EDE partner sites to identify data trends that could indicate potential misconduct or noncompliant behavior or activities. Past investigations using system monitoring data have borne results that show a connection between potentially noncompliant, fraudulent, or abusive behavior and the trends we monitor. For example, we monitor the number of unsuccessful person searches on approved Classic DE and EDE partner sites because, in our experience, there is often a correlation between a high volume of unsuccessful person searches and noncompliant, fraudulent, or abusive behavior. The person search feature is intended to help agents, brokers, and web-brokers find consumer applications to prevent duplicate enrollments, but in our experience, bad actors use this feature to find applications and make plan changes or NPN changes without consumer knowledge or consent, negatively impacting the consumer and compliant agents, brokers, and web-brokers. However, because bad-acting agents,

brokers, or web-brokers often do not have exact or complete consumer information, their person searches may not direct them to the consumer applications they are searching for, frequently leading them to run more unsuccessful searches using slightly different, yet incomplete or otherwise inaccurate, consumer information. Therefore, we monitor and would, under this proposal, continue to monitor, unsuccessful person searches on approved Classic DE and EDE partner websites to identify potential bad-actors.

Discovering agency-wide resources, such as company practices or directives, training manuals, or marketing material that suggests agency endorsement of or involvement in misconduct or noncompliant behavior or activities is another source of information we would use to determine whether to engage in a compliance review or take an enforcement action against the lead agents or other agents, brokers, or web-brokers who may be involved in the misconduct or noncompliant behavior or activities. We have seen agency-wide resources, such as training manuals or marketing documents, that contain information, promotions, or sales tactics suggestive of agency endorsement of or involvement in misconduct or noncompliant behavior or activities. For example, as part of compliance investigations and enforcement actions, we have seen agency documentation instructing agents and brokers who work at the agency to fabricate enrollee or applicant incomes on eligibility applications submitted to the FFEs or SBE-FPs to ensure the enrollee or applicant has a zero-dollar policy.¹⁵⁹ This can lead to consumers being enrolled in QHPs offered through Exchanges with zero-dollar premiums without their knowledge or consent. This, in turn, can lead to consumers owing money to the IRS during tax reconciliation because they were receiving APTC amounts but were not aware of this because their monthly premium was zero dollars.^{160 161}

¹⁵⁹ Fabricating an individual's income violates §§ 155.220(j)(2)(ii) and (j)(2)(ii)(E), which generally state that agents, brokers, and web-brokers must "Provide the Federally-facilitated Exchanges with correct information . . ." and household income projections must only be submitted when ". . . the consumer or the consumer's authorized representative . . . has knowingly authorized and confirmed as accurate." The same standards and requirements apply to SBE-FP States. See 45 CFR 155.220(l).

¹⁶⁰ Appleby, J. (2024, May 7). *How the government is trying to stop rogue brokers from plaguing ACA enrollees*. KFF News, <https://www.npr.org/sections/health-shots/2024/05/07/1249417648/aca-health-insurance-brokers-obamacare-stop-fraud>.

Additionally, as part of these investigations and actions, we have reviewed agency procedures and directives instructing agents and brokers who work at the agency to not speak with the enrollee or applicant prior to enrolling them in a plan.¹⁶² Not speaking with enrollees or applicants prior to submitting an enrollment may cause the consumer to receive incorrect APTC amounts, which the consumer will have to repay in the future, or may cause a consumer to receive data matching issues (DMIs), which, if left unresolved, can lead to loss of coverage.¹⁶³ Upon eligibility application submission, certain consumer data is checked against trusted data sources to ensure a match between what is in the application submission and the information HHS receives from the trusted data source(s). If the trusted data source does not have the consumer data or the data is inconsistent with the information provided on the application, a DMI is generated. A non-exhaustive list of DMIs include the Annual Income DMI, Citizenship/Immigration DMI, and American Indian/Alaskan Native Status DMI. Certain DMIs may lead to loss of Exchange coverage, including a Citizenship/Immigration DMI, which occurs when the consumer is unable to verify an eligible citizenship or lawful presence status.

Once we determined there is information or evidence suggesting there may be agency-level endorsement of or involvement in misconduct or noncompliant behavior or activities, we would then determine if the agency was involved in or facilitated the submission of the consumer's eligibility application or enrollment to the FFEs or SBE-FPs. This would also inform our determination of whether to engage in a compliance review or take enforcement action against the lead agent(s) or other agents, brokers, or web-brokers who may be involved in the misconduct or

¹⁶¹ Consumers who find errors on their Form 1095-A, which contains information on APTC received, should contact the Marketplace Call Center to report any errors and discuss next steps for resolution. Additional information can be found here: <https://www.healthcare.gov/taxes/>.

¹⁶² Failing to speak with the enrollee or applicant prior to enrolling them in a QHP offered on the Exchange violates § 155.220(j)(2)(ii)(A), which states eligibility application information must be "reviewed by and confirmed to be accurate by the consumer . . ." prior to submission. It also calls in question whether the agent, broker, or web-broker complied with the requirement in § 155.220(j)(2)(iii) to obtain and document the consumer's consent prior to assisting the consumer with the Exchange application and enrollment.

¹⁶³ For information on how to address any tax implications of APTC, consumers should refer to resources available at: <https://www.healthcare.gov/taxes/>.

¹⁵⁸ We would look at agent, broker, and web-broker email addresses or other submitted information, such as consent documentation or the NPN listed on the Exchange eligibility application, to help discern if there is a connection or relationship between an agent, broker, or web-broker and an agency.

noncompliant behavior or activities. Determining if the agency was involved in or facilitated the submission of the consumer's eligibility application or enrollment to the FFEs or SBE-FPs would involve looking at the agency's business practices and what resources it provides its agents, brokers, or web-brokers. In our experience, the more resources an agency allocates to supporting the ability of an agent, broker, or web-broker to enroll enrollees and applicants, the more indicative it is that the agency facilitates the submission of the eligibility application and enrollments to an FFE or SBE-FP. For example, if an agency provides an agent, broker, or web-broker with a training program, an email address with an agency domain, and access to other agency resources that support enrollment, such as a call center that intakes potential consumers to gather basic information, these are all indications the agency wants to make enrollments easier for the agent, broker, or web-broker and that the agency facilitates the submission of Exchange applications and enrollments. As previously noted, the inclusion of the business NPN is another clear indication of the agency's involvement in the submission of the Exchange application or enrollment transaction. This would be another critical piece of information that we would consider as we determine whether to engage in a compliance review or take enforcement action against the lead agent(s) or other agents, brokers, or web-brokers who may be involved in the misconduct or noncompliant behavior or activities.

We seek comment on these proposals. In particular, we are interested in comments from States as to the specific or unique characteristics of their agency oversight policies and procedures, including how they define or describe the term "lead agent," or whatever term of art each State uses to capture our definition of "lead agent" in this preamble, as well as suggestions from States for ways to enhance collaboration and alignment of our oversight and enforcement of agencies that assist consumers applying for and enrolling in QHPs through the FFEs and SBE-FPs. We are also interested in comments from Classic DE and EDE partners, issuers, and other interested parties regarding whether we should consider an agent, broker, or web-broker that allows their NPN to be used by other agents, brokers, or web-brokers to be a lead agent and potentially held responsible for misconduct or noncompliant behavior or activities

committed by another agent, broker, or web-broker using their NPN.

b. System Suspension Authority

We propose to amend § 155.220(k)(3), which outlines our authority to immediately suspend an agent's or broker's ability to transact information with the Exchange if we discover circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is sufficiently remedied or sufficiently mitigated to HHS' satisfaction. Specifically, we propose to add language to reflect that § 155.220(k)(3) system suspensions may be imposed in instances in which we discover circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260,¹⁶⁴ until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. We believe these amendments are necessary and appropriate Exchange program integrity measures to support the efficient administration of Exchange activities, reduce fraud and abuse, and protect Exchange applicant or enrollee personally identifiable information (PII).

Section 1312(e) of the ACA provides the Secretary with authority to establish procedures under which a State may allow agents or brokers to (1) enroll individuals and employers in any QHPs in the individual or small group market once the plan is offered through an Exchange in the State; and (2) assist individuals in applying for PTC and CSRs for plans sold through an Exchange. In addition, section 1313(a)(5)(A) of the ACA directs the Secretary to provide for the efficient and non-discriminatory administration of Exchange activities and to implement any measure or procedure the Secretary determines is appropriate to reduce fraud and abuse. Section 1321(a) of the ACA provides broad authority to the Secretary to establish standards and issue regulations to implement the

¹⁶⁴ Section 155.220(d)(3) requires agents and brokers to enter into a Privacy and Security Agreement pursuant to which they agree to comply with Exchange privacy and security standards adopted consistent with § 155.260. There are two Privacy and Security Agreements between CMS and the agent, broker, and web-broker for FFEs and SBE-FPs: (1) one is for the individual market FFEs and SBE-FPs, and (2) one is for the FF-SHOPs and SBE-FP-SHOPs.

statutory requirements related to Exchanges, QHPs, and other components of title I of the ACA, which includes sections 1312 and 1313. Section 1321(a) of the ACA also provides the Secretary with authority to implement other requirements as the Secretary determines appropriate. In prior rulemakings, we used these authorities to adopt § 155.220, which establishes standards and requirements applicable to agents, brokers, and web-brokers assisting individuals, employers, or employees with enrollment in QHPs offered through the FFEs, including the system suspension authority in § 155.220(k)(3). Consistent with § 155.220(l), the FFE standards and requirements in § 155.220 also apply to agents, brokers and web-brokers that assist with or facilitate enrollment in States with SBE-FPs.¹⁶⁵

As we explained in the 2020 Payment Notice,¹⁶⁶ to promote information technology system security in the FFEs and SBE-FPs, including the protection of consumer data, we codified paragraph § 155.220(k)(3) to capture HHS' authority to immediately suspend an agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.¹⁶⁷ We explained this provision was necessary and appropriate to ensure that HHS can take immediate action to stop unacceptable risks to Exchange operations or systems posed by agents and brokers, as well as take immediate action to protect sensitive consumer data.¹⁶⁸ This provision currently applies to agents and brokers who, once registered under § 155.220(d)(1), obtain credentials that provide access to Exchange systems that may be misused in a manner that threatens the security of the Exchange's operations or information technology systems. When an agent's or broker's ability to transact information with the Exchange is

¹⁶⁵ This includes the extension of the system suspension authority under § 155.220(k)(3).

¹⁶⁶ 84 FR 17517. Also see the 2020 Payment Notice proposed rule, 84 FR 272.

¹⁶⁷ This is similar to the authority captured at § 155.221(e) that applies to DE entities and permits HHS to immediately suspend the DE entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.

¹⁶⁸ 84 FR 17517. Also see the 2020 Payment Notice proposed rule, 84 FR 272.

suspended under this authority, they remain registered with the FFEs and are authorized to assist FFE and SBE–FP consumers using the Exchange (or side-by-side) Pathway¹⁶⁹ and the Marketplace Call Center, unless and until their Exchange Agreements are suspended or terminated under § 155.220(f) or (g).¹⁷⁰

We propose to amend § 155.220(k)(3) to reflect that HHS may immediately suspend the agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) and the privacy and security standards under § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction.¹⁷¹ We are pursuing these amendments in the interest of transparency and to more clearly capture in regulation when HHS may invoke this authority. As noted above, we also believe these are necessary and appropriate Exchange program integrity measures to support the efficient administration of Exchange activities, reduce fraud and abuse, and protect Exchange applicant or enrollee PII.

We continuously monitor for behaviors or activities related to Exchange operations or access to Exchange systems and enrollee or applicant PII that we believe, based on our experience overseeing agents and brokers on the FFEs and SBE–FPs, may be indicative of misconduct or noncompliance with applicable HHS Exchange standards or requirements.

Our experience overseeing agents and brokers on the FFEs and SBE–FPs includes past completed agent, broker, and web-broker investigations and enforcement actions, and observations of behavior by agents and brokers that may not comply with the standards of conduct at § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260 and that could endanger the accuracy of Exchange eligibility determinations, applicant or enrollee PII, or Exchange operations or systems in a number of ways.

A non-exhaustive list of agent or broker data we monitor to identify behaviors or activities that may be indicative of misconduct or noncompliance with applicable HHS Exchange standards or requirements includes: (1) the number of Exchange transactions submitted to the FFEs or SBE–FPs to change enrollee or applicant eligibility application information or plan selections, (2) the volume of person search activities, (3) the number of submitted eligibility applications with missing Social Security Numbers (SSNs), (4) the number of enrollments submitted within a specified time-frame, and (5) the volume of submitted eligibility applications with NPN changes. We also review and consider complaints from enrollees, applicants, and other individuals or entities concerning agent and broker activities.¹⁷²

Once we receive a complaint or identify concerning or anomalous data, we review the complaint and/or data to determine if there is information that suggests the impacted enrollees or applicants may have authorized the agent or broker to submit an Exchange eligibility application, or an update to an existing enrollment, on their behalf. We then review the available documentation and application details and may contact the agent or broker and interview Exchange enrollees or applicants to gather more information. Depending on the results of this preliminary investigation, agents or brokers may be provided additional education and technical assistance, or we may implement a system suspension under § 155.220(k)(3) if we discover circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems.

There are different factors we consider when deciding whether to implement a system suspension under § 155.220(k)(3) or offer technical assistance. These factors include the

number of times that our data, including complaints we receive, indicate that an agent or broker may have engaged in misconduct or noncompliance with applicable HHS Exchange standards or requirements, the number of consumers impacted by their suspected misconduct or noncompliant behavior or activities, and the severity of the alleged misconduct or noncompliant behavior or activities. We would continue these practices for system suspensions under the proposed updates in this rule to § 155.220(k)(3), which would expand the bases for imposing a system suspension to include situations that pose unacceptable risk to the accuracy of Exchange eligibility determinations, Exchange applicants, and Exchange enrollees. This proposed amendment to § 155.220(k)(3) aligns with the approach outlined in the 2020 Payment Notice (84 FR 17517) and is in response to misconduct and noncompliant behavior and activities by agents and brokers that we have observed in connection with our oversight of the FFEs and SBE–FPs. This proposal is designed to promote information technology system security in the FFEs and SBE–FPs, including the protection of consumer data, reduce fraud and abuse, and support the efficient administration of Exchange activities.

Consistent with the existing framework, in circumstances where we would impose a system suspension under the proposed amendments to § 155.220(k)(3), we would notify the agent or broker of the suspension and they would have an opportunity to submit evidence and information or to demonstrate that the circumstances of the incident, breach, or noncompliance are sufficiently remedied or mitigated to HHS' satisfaction to warrant lifting the suspension to reinstate their system access. We would review such evidence and information submitted by the agent or broker to determine if the circumstances of the incident, breach, or noncompliance are sufficiently remedied or mitigated to warrant lifting the suspension to reinstate their system access. For example, we anticipate receiving documentation of consumer consent and/or review and confirmation of the accuracy of the Exchange eligibility application information and assessing whether the documentation complies with § 155.220(j)(2)(ii) and (iii) for consumers cited in the suspension notice from agents and brokers we system suspend under § 155.220(k)(3). If such evidence or information sufficiently remedies or mitigates the incident, breach or noncompliance to our satisfaction, we would lift the

¹⁶⁹ For more information on the Exchange Pathway, please see, CMS. (2016, Nov. 8). *Health Insurance Marketplace Guidance: Role of Agents, Brokers, and Web-brokers in Health Insurance Marketplace*. https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Role-of-ABs-in-Marketplace_Nov-2016_Final.pdf.

¹⁷⁰ 84 FR 17517.

¹⁷¹ We are not proposing to add a reference to web-brokers as part of these amendments to § 155.220(k)(3) because, as DE entities, web-brokers are subject to the system suspension authority at § 155.221(e). See § 155.221(a)(2). This is similar to the authority captured at § 155.221(e) that applies to DE entities and permits HHS to immediately suspend the DE entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.

¹⁷² Complaints may be submitted to the Marketplace Call Center. See <https://www.cms.gov/files/document/agent/broker-help-desks.pdf>.

suspension and reinstate Exchange system access for the agent or broker.

In cases where such evidence and information does not sufficiently remedy or mitigate the circumstances of the incident, breach or noncompliance to HHS' satisfaction (including situations where there is no response from the agent or broker), we would not lift the suspension under § 155.220(k)(3) to reinstate the agent's or broker's system access and would pursue a suspension or termination of the agent's or broker's Exchange Agreements under § 155.220(g). As previously noted, agents and brokers whose ability to transact information with the Exchange is suspended under § 155.220(k)(3) remain registered with the FFEs and are authorized to assist consumers using the Exchange (or side-by-side) pathway and the Marketplace Call Center, unless and until their Exchange Agreements are suspended or terminated under § 155.220(f) or (g).

We are pursuing these amendments at this time in light of recent increases in behavior by agents and brokers that indicate potential violations of § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260 and endangers applicant or enrollee PII or Exchange program integrity in a manner that poses unacceptable risk to the accuracy of Exchange eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems.

Since the start of PY 2024 Open Enrollment, we have seen an increase in complaints from enrollees, applicants, and other individuals and entities to the Agent/Broker Help Desk regarding enrollments submitted without enrollee or applicant consent, enrollee or applicant eligibility applications submitted with incorrect information and without enrollee or applicant review or confirmation of the eligibility application information, and changes to enrollee or applicant eligibility applications made without enrollee or applicant consent.¹⁷³ A significant portion of these complaints have involved unauthorized changes to the plans in which enrollees or applicants were enrolled, impacting the ability of enrollees or applicants to utilize their desired coverage and access care.¹⁷⁴

¹⁷³ CMS. (2024, July 19). *CMS Statement on System Changes to Stop Unauthorized Agent and Broker Marketplace Activity*. <https://www.cms.gov/newsroom/press-releases/cms-statement-system-changes-stop-unauthorized-agent-and-broker-marketplace-activity>.

¹⁷⁴ When consumers call the Marketplace Call Center to report unauthorized enrollments, we resolve their complaints through a combination of

Unauthorized plan changes may harm enrollees or applicants by removing them from their selected plan and placing them in another plan that may not provide coverage that meets their needs (for example, different plans can have different formularies and provider networks). Unauthorized enrollments can also involve situations where individuals are enrolled in an Exchange plan without having an existing Exchange plan. Being enrolled in an Exchange plan, including in the case of an unauthorized enrollment, may impact a consumer's future ability to enroll in health insurance through the Exchange or enroll in Medicare or Medicaid, as a consumer may not enroll in more than one plan simultaneously. Unauthorized enrollments may also create premium costs for the consumer if the unauthorized enrollment is in a non-zero-dollar premium plan. Unauthorized plan changes and enrollments cost the consumer time to learn about and resolve the discrepancy and either (1) unenroll from a plan they did not want, or (2) change the plan to one that better meets their needs.

Additionally, submission of eligibility applications with inaccurate enrollee or applicant data, such as an incorrect income, may cause harm by providing the enrollee or applicant with an incorrect APTC amount. An incorrect APTC amount can result in a consumer erroneously receiving a zero-dollar monthly premium. Because the consumer does not receive monthly billing notifications due to the zero-dollar premiums, they may not know they were enrolled or that their eligibility application information was incorrect. However, once the consumer files their taxes, a reconciliation may reveal that the consumer must repay the incorrect APTC amount they were receiving. By their nature, these unauthorized enrollments and plan changes involve the misuse of enrollee or applicant PII, and they threaten the efficient administration of the Exchange and the accuracy of Exchange eligibility determinations.

Our experience monitoring compliance with the new requirements

the following: (1) we review the complaint to verify that the consumer's plan switch was unauthorized and identify the plan that the consumer wants to be enrolled in; (2) we instruct the issuer offering the plan the consumer wants to be enrolled in to reinstate the consumer's enrollment in that plan as if it had not been terminated. The insurer is instructed to cover all eligible claims incurred and accumulate all cost sharing toward applicable deductibles and annual limits on cost sharing; and/or (3) consumers receive updated tax forms and information via a 1095-A that is generated by HHS and which the enrollee sends to the IRS to prevent adverse tax implications as a result of the unauthorized plan switch activity.

in § 155.220(j)(2)(i), (ii), and (iii) has also shown that agents, brokers, and web-brokers are engaging in misconduct or noncompliant behavior or activities. For example, their consumer consent and eligibility application information review documentation often lacks the required content specified in § 155.220(j)(2)(ii) or (iii) that demonstrates the applicant or enrollee has taken an action to provide consent or confirm the accuracy of the eligibility application information prior to submission to the Exchange. For example, we have seen consent documentation that solely lists numbers that the agent, broker, or web-broker claims tie back to the consumer's IP address, which we cannot verify and does not meet the consent documentation requirements of § 155.220(j)(2)(iii). Additionally, we have received consent documentation that is merely a name, typed using a cursive script, with no indication the consumer took an action to confirm their consent to the assistance provided by the agent, broker, or web-broker, such as a text message response, email response, or signature.¹⁷⁵ The proposed amendments to § 155.220(k)(3) to permit immediate system suspensions would support HHS' efforts to take immediate action to prevent further enrollee, applicant, Exchange operational, Exchange information technology, or Exchange program integrity harm caused by agents and brokers engaged in these types of misconduct.

Though we believe our current authority in § 155.220(k)(3) allows HHS to implement system suspensions broadly based on circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems, in light of the increasing complaints about unauthorized enrollments, we propose amendments to § 155.220(k)(3) to increase transparency concerning the reach and application of system suspensions and more accurately capture in regulation when HHS may invoke this authority. These proposed amendments would allow HHS to immediately respond to discovered risks to the accuracy of Exchange eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems. They would also provide agents and brokers with an increased understanding of our

¹⁷⁵ A typed name using a cursive script, alone, makes it impossible for CMS to determine if the consumer, or their authorized representative, provided the consent and typed the signature. In these situations, supplemental documentation is required for CMS to assess compliance with the consent requirements of § 155.220(j)(2)(iii).

approach to implement system suspensions. The proposed amendments would also better encapsulate the original intent of the § 155.220(k)(3) suspension authority, which included protecting against unacceptable risk to consumer Exchange data.

We note that the types of misconduct or noncompliant behaviors or activities that could lead to a system suspension under § 155.220(k)(3) could also lead to an enforcement action under § 155.220(g). However, there are important distinctions between these authorities. For example, system suspensions under § 155.220(k)(3) allow HHS to immediately suspend an agent or broker's system access. These suspensions differ from suspensions or terminations under § 155.220(g) because they do not suspend or terminate the agent's or broker's Exchange Agreement(s).¹⁷⁶ Rather, they prevent agents or brokers from submitting Exchange applications and enrollments through the Direct Enrollment Pathways, whether Classic DE or EDE. However, while a system suspension is in place, the agent or broker remains registered with the FFEs, unless and until their Exchange Agreements are suspended or terminated under § 155.220(f) or (g). As such, a system suspension does not prohibit the agent or broker from enrolling enrollees or applicants via the Marketplace Call Center on a three-way call with the enrollees or applicants or side-by-side with an enrollee or applicant on *HealthCare.gov* (also known as the "Exchange Pathway").¹⁷⁷ In cases where

there is imminent danger to applicants' or enrollees' PII or to Exchange program integrity in such a manner that poses unacceptable risk to the accuracy of Exchange eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems from the misconduct of agents, brokers, or web-brokers, system suspensions under the proposed amendments to § 155.220(k)(3) would provide a more immediate action to protect applicants' or enrollees' PII and the efficient administration of the Exchange, as well as reduce potential fraud and abuse.

In contrast, an enforcement action under § 155.220(g) to suspend or terminate an agent's, broker's, or web-broker's Exchange Agreement(s) results in the agent, broker, or web-broker no longer being registered with the FFEs.¹⁷⁸ When an agent's, broker's, or web-broker's Exchange Agreements are suspended, or following the termination of the agent's, broker's, or web-broker's Exchange Agreements, the agent, broker, or web-broker is also no longer permitted to assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through an FFE or SBE-FP, or assist individuals in applying for APTC and CSRs for QHPs. As such, these agents, brokers, and web-brokers cannot submit Exchange applications and enrollments through any of the available pathways—through Classic DE, EDE, the Marketplace Call Center, and/or through the Exchange pathway.

Though we would only initiate enforcement action under § 155.220(k)(3) against agents and brokers based on data or other information that suggest noncompliance or misconduct, we recognize that data or other information could suggest there is noncompliance or misconduct by a compliant agent or broker. For example, in some instances, this could occur if an agent or broker works largely or exclusively with a specific group of consumers, including those who live in low-income communities, communities where life changes necessitating eligibility application changes may be more common, or communities where some consumers may not have SSNs but are nonetheless eligible for Exchange coverage. Consistent with the existing framework, when pursuing system suspensions under § 155.220(k)(3), as proposed to be amended, agents and

without sharing their log-in credentials with the agent or broker.

¹⁷⁸ See § 155.220(g)(4) and (5)(iii).

brokers would be notified of the system suspension and would have an opportunity to submit evidence or other information (such as documentation of consumer consent and review of the eligibility application information that is compliant with § 155.220(j)(2)(ii) and (iii)), to demonstrate that the circumstances of the incident, breach, or noncompliance concerns are sufficiently remedied or mitigated to HHS' satisfaction to merit reinstatement of their system access. Where there is clear evidence of compliance, compliant agents and brokers would be able to quickly respond to or otherwise remediate the risks identified by HHS that led to the system suspension under § 155.220(k)(3) such that their system access could be reinstated more swiftly than the lifting of a suspension or reinstatement of an agent's or broker's Exchange Agreement(s) following an enforcement action under § 155.220(g).

We seek comment on this proposal.

c. Model Consent Form Updates

We are proposing to modify the Model Consent Form that was created as part of the 2024 Payment Notice (88 FR 25809 through 25811).¹⁷⁹ Our proposed modifications include updating the Model Consent Form to include a section for documentation of consumer review and confirmation of the accuracy of their Exchange eligibility application information under § 155.220(j)(2)(ii)(A)(1)–(2), as well as scripts agents, brokers, and web-brokers could use when meeting the requirements codified at § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A)–(C) via an audio recording.

Agents, brokers, and web-brokers are required to obtain consumer consent prior to assisting with and facilitating enrollment in coverage through FFEs and SBE-FPs or assisting an individual with applying for APTC and CSRs for QHPs. Until we finalized new requirements related to consumer consent in the 2024 Payment Notice, there was no mandate to document the receipt of consent of the consumer or their authorized representative, or to maintain such documentation. The absence of a consent documentation requirement led to disputes between consumers and agents, brokers, and web-brokers that were difficult for us to adjudicate because neither party had documentary proof of consent. In the 2024 Payment Notice (88 FR 25809 through 25811), we finalized regulations

¹⁷⁹ CMS. (2022, December 14). CMS Model Consent Form for Marketplace Agents and Brokers. PRA package (CMS–10840, OMB 0938–1438). <https://www.cms.gov/files/document/cms-model-consent-form-marketplace-agents-and-brokers.pdf>.

¹⁷⁶ Consistent with § 155.220(d), there are currently three Exchange Agreements with CMS that extend to agents or brokers assisting consumers in the FFEs and SBE-FPs: (1) the Agent Broker General Agreement for Individual Market FFEs and SBE-FPs, (2) the Agent Broker Privacy and Security Agreement for Individual Market FFEs and SBE-FPs, and (3) the Agent Broker SHOP Privacy and Security Agreement. Web-brokers assisting consumers in the FFEs and SBE-FPs are required to sign the Web-broker General Agreement, and web-brokers who are primary Enhanced Direct Enrollment (EDE) entities that assist consumers in the FFEs and SBE-FPs are required to sign the EDE Business Agreement and the Interconnection Security Agreement. In addition, each individual agent or broker who wishes to include the business entity NPN on Exchange eligibility applications must also complete the annual registration process, take the required trainings, and sign the applicable Exchange Agreements with CMS for the applicable plan year using their individual NPN.

¹⁷⁷ In this pathway, registered agents and brokers help a consumer obtain an eligibility determination and select a plan directly on *HealthCare.gov*. The consumer creates an account, logs in to the *HealthCare.gov* website with a consumer account, and "drives" the process; the agent or broker does not log in to *HealthCare.gov*. Generally, the Exchange Pathway requires the agent or broker to be sitting side-by-side with the consumer because the consumer must sign in to *HealthCare.gov*

requiring receipt of consent of the consumer or their authorized representative to be documented.¹⁸⁰ Under these regulations, the consent documentation must contain certain minimum elements as enumerated in § 155.220(j)(2)(iii)(B) and must be retained by the assisting agent, broker, or web-broker for a minimum of 10 years and produced to HHS upon request in response to monitoring, audit, and enforcement activities pursuant to § 155.220(j)(2)(iii)(C). Our goal in codifying these consent documentation requirements was to minimize the risk of fraudulent activities, such as unauthorized enrollments, and help us resolve disputes and adjudicate claims related to the provision of consumer consent.

We also finalized regulations in the 2024 Payment Notice (88 FR 25804 through 25809) requiring agents, brokers, and web-brokers assisting with and facilitating enrollment in coverage through FFEs and SBE-FPs or assisting an individual with applying for APTC and CSRs for QHPs to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative prior to application submission.¹⁸¹ Under these regulations, this documentation must contain certain minimum elements as enumerated in § 155.220(j)(2)(ii)(A)(1) and must be retained by the assisting agent, broker, or web-broker for a minimum of 10 years and produced to HHS upon request in response to monitoring, audit, and enforcement activities pursuant to § 155.220(j)(2)(ii)(A)(2). Our goal in codifying these requirements was to minimize the risk of fraudulent activities, such as providing false information to the Exchange, help us resolve disputes and DMIs and adjudicate claims related to inaccurate eligibility information on submitted applications, and ensure consumers receive accurate eligibility determinations and do not receive incorrect APTC determinations, which may result in consumers owing money during tax reconciliation.

The Model Consent Form¹⁸² created and provided to agents, brokers, and web-brokers on June 30, 2023, has been used by agents, brokers, and web-brokers, either as is or as a starting point for creating their own consent

documentation. However, no Model Consent Form was created for agents, brokers, and web-brokers to use to meet the documentation of consumer review and confirmation of the accuracy of the eligibility application information requirements enumerated in § 155.220(j)(2)(ii)(A)(1). Since the 2024 Payment Notice requirements went into effect, agents, brokers, and web-brokers have asked us to provide a model documentation that they could use to meet these requirements under § 155.220(j)(2)(ii). We are proposing to update the Model Consent Form to include a section for documentation of consumer review and confirmation of the accuracy of their Exchange eligibility application information in response to these requests. This proposed addition to the Model Consent Form is meant to provide clarity to agents, brokers, and web-brokers on how to meet the regulatory requirements under § 155.220(j)(2)(ii) and help them comply with this regulation by providing a standardized form they may use to do so. Furthermore, we believe providing a clearly written Model Consent Form would provide more consumer clarity and assurance that the agent, broker, or web-broker they are working with is complying with § 155.220(j)(2)(ii).

Because the requirements of § 155.220(j)(2)(ii)(A) and (j)(2)(iii) can be met via an audio recording, we are also proposing to create appendices to the Model Consent Form that would contain scripts agents, brokers, and web-brokers may use to document compliance with these requirements via an audio recording. Our goal is to provide agents, brokers, and web-brokers who assist consumers verbally with guidance on meeting the consent and eligibility application review documentation requirements contained in § 155.220(j)(2)(iii) and (j)(2)(ii)(A), respectively, similar to how the current Model Consent Form helps agents, brokers, and web-brokers documenting consent via a physical document with handwritten signatures demonstrate compliance with the new consent documentation requirements.

The proposed scripts, to the extent they are utilized by agents, brokers, and web-brokers, would help ensure agents, brokers, and web-brokers are following the regulatory requirements when enrolling consumers. We believe this would reduce consumer harm by reducing unauthorized enrollments, which can result in financial harm if a consumer receives an improper APTC amount upon enrollment. We also believe this proposal would clarify and simplify how regulated entities can

meet regulatory requirements. This proposal does not involve any revisions to § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A)–(C). If finalized as proposed, it would not be mandatory for agents, brokers, or web-brokers to use the amended Model Consent Form or new scripts to comply with the requirements set forth in § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A)–(C).

We seek comment on these proposals.

3. Requirement for Notification of Tax Filers and Consumers Who Have Failed To File and Reconcile APTC for Two Consecutive Tax Years (§ 155.305)

As part of the 2024 Payment Notice, we changed the FTR process such that an Exchange may only determine enrollees ineligible for APTC due to their FTR status after a tax filer (or a tax filer's spouse, if married) has failed to file a Federal income tax return and reconcile their APTC for 2 consecutive years (specifically, years for which tax data will be utilized for verification of household income and family size). However, in that rule, we did not impose a requirement for Exchanges to notify enrollees or their tax filers that the applicable tax filer failed to file and reconcile. In the 2025 Payment Notice, we imposed a requirement for Exchanges to send direct or indirect notices for the first year in which the tax filer was determined to have failed to file and reconcile. We are now proposing to revise § 155.305(f)(4) to require Exchanges to send a direct or indirect notice (as defined below) to enrollees or their tax filers who have not filed their Federal income tax return and reconciled their APTC for two consecutive tax years.

To our knowledge, when FTR operations were conducted in prior years before the new two-year process that was implemented as part of the 2023 Payment Notice (87 FR 27208), it was the practice of Exchanges to send notices to enrollees or their tax filers (or both) who were at risk of being determined ineligible for APTC due to failing to file and reconcile APTC for the previous tax year. Enrollees or their tax filers would be sent notices after the initial identification of FTR status prior to Open Enrollment and/or during the FTR Re-check process, depending on the process of the Exchange. In addition, it has also been the practice of Exchanges to notify enrollees or their tax filers (or both) of their FTR status when they attest that they have filed their Federal income tax return and reconciled APTC, but IRS data has not been updated to reflect their compliance with the requirement to file and reconcile. FTR Re-check is the post

¹⁸⁰ 45 CFR 155.220(j)(2)(iii).

¹⁸¹ See § 155.220(j)(2)(ii).

¹⁸² CMS. (2022, December 14). *CMS Model Consent Form for Marketplace Agents and Brokers*. PRA package (CMS–10840, OMB 0938–1438). <https://www.cms.gov/files/document/cms-model-consent-form-marketplace-agents-and-brokers.pdf>.

Open Enrollment verification process for consumers with either a one-tax year or two-tax year FTR status. Exchanges using the Federal eligibility and enrollment platform begin FTR Re-check operations by cross referencing past FTR statuses, consumers' attestations made on the current plan year's applications if applicable, and IRS income data to confirm whether tax filers filed their Federal income tax returns and reconciled APTC for one or both of the most recent tax years for which the IRS provides data to Exchanges through the Federal Data Services Hub. FTR Re-check generally happens after Open Enrollment ends on January 15 for Exchanges using the Federal eligibility and enrollment platform.

We are proposing to require, consistent with the notice requirement in § 155.305(f)(4)(i), that, for a consumer identified as having a two-tax year FTR status, Exchanges provide either a direct notification to the tax filer that the Exchange has determined that the tax filer or their spouse has failed to file and reconcile their APTC for two consecutive tax years ("direct notice"), or a notification to the consumer stating that they may be at risk of losing their APTC and educating them about the requirement to file their Federal income taxes and reconcile their APTC ("indirect notice or "combined notice"). The proposed revisions would require Exchanges to send a direct notice or a combined notice for consumers identified as having both a one tax-year, and a two tax-year, FTR status. In addition to these notices, consumers who lose their APTC after the FTR Recheck process will also receive the eligibility determination notice (EDN) under § 155.330(e)(1)(ii).

This proposed requirement represents the minimum requirement for Exchanges to provide sufficient notice to enrollees or their tax filer (or both) about the need to file their Federal income tax return and reconcile APTC, and the risks of failing to do so. Consistent with operations before the COVID-19 pandemic, Exchanges on the Federal platform provide enrollees or their tax filers (or both) with more notifications that go above and beyond the minimum requirement, and they will continue to do so. Specifically, Exchanges on the Federal platform send out combined notices prior to Open Enrollment, and then again after FTR Recheck for both the one-tax year and two-tax year FTR populations. Tax filers who are identified as being in either a one-tax year or two-tax year FTR status prior to Open Enrollment, and then again after FTR Recheck, also receive

direct notices. HHS encourages State Exchanges to adopt these best practices as well to provide multiple points of contact to the enrollee or tax filer (or both) on the requirement to file and reconcile their APTC to remain eligible for APTC. However, due to the concerns of interested parties about the difficulty required to notify both enrollees and tax filers, we are choosing to propose requiring only notifying either the consumer or the tax filer for the second tax year FTR population, and we acknowledge that most State Exchanges' current practice already involves multiple notifications for consumers who are at risk of losing their APTC. As the proposal only requires one notification to consumers in a two-tax year FTR status, similarly to the current rules only requiring one notice for one-tax year FTR status consumers, it is possible that Exchanges could choose to send this notice with Open Enrollment prior to the plan year where the enrollee may lose APTC or during the plan year in which the Exchange would remove APTC.

Therefore, we are proposing to add a section to § 155.305(f)(4)(ii) stating that if HHS informs an Exchange that APTC payments were made on behalf of either the tax filer or the tax filer's spouse, if applicable, for two consecutive tax years and they did not comply with the requirement to file an income tax return for those years as required by 26 U.S.C. 6011, 6012 and applicable regulations, then the Exchange must send a notice as directed in proposed subparagraphs (f)(4)(ii)(A) or (B) (or both). In proposed subparagraph (f)(4)(ii)(A), we propose to require an Exchange to send a notice directly to the tax filer informing the tax filer that they have been identified as failing to file and reconcile for two consecutive tax years, educating them about the requirement to file and reconcile APTC, and warning them that they are at risk for losing APTC eligibility because they, or their spouse, if applicable, did not file their Federal income tax return for two consecutive tax years. Exchanges that choose to send these direct notices must comply with statutory requirements to protect Federal tax information (FTI) per 26 U.S.C. 6103. For Exchanges on the Federal platform, these direct notices are sent via U.S. postal mail only, and no electronic copy of the notice is retained to protect FTI. Finally, we propose to add new subparagraph (f)(4)(ii)(B), which requires an Exchange to send an indirect notice to either the tax filer or their enrollee that does not disclose FTI but educates the enrollee or their tax filer on the requirement to file

their Federal income tax return and reconcile APTC.

These proposed changes would ensure that either all tax filers or, if applicable, their enrollees who are identified as having an FTR status for two consecutive tax years would receive educational notices detailing the requirement to file and reconcile their APTC at least twice before losing their APTC eligibility; they would receive a notice for the first year they were found to be in an FTR status, and then again the second consecutive tax year they were found to have failed to file and reconcile their APTC.

As discussed in 2025 Payment Notice (89 FR 26299), we want to continue to ensure tax filers and enrollees are provided appropriate education on the requirement to file and reconcile their APTC before being determined ineligible for APTC for failing to file and reconcile for a second consecutive tax year. Sample notices would be available at <https://www.cms.gov/marketplace/in-person-assisters/applications-forms-notices/notices>.

We seek comment on this proposal.

4. Timeliness Standard for State Exchanges To Review and Resolve Enrollment Data Inaccuracies § 155.400(d)(1)

We propose to add § 155.400(d)(1) to codify HHS guidance¹⁸³ that, within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in an State Exchange (hereinafter referred to as "State Exchange issuer") that includes a description of an inaccuracy that meets the requirements at § 156.1210(a)–(c) and all the information that the State Exchange requires or requests to properly assess the inaccuracy, the State Exchange must review and resolve the State Exchange issuer's enrollment data inaccuracies and submit to HHS a description of the resolution of any inaccuracies described by the State Exchange issuer that the State Exchange confirms to be inaccuracies in a format and manner specified by HHS.¹⁸⁴ This proposed policy aligns with the existing requirement at § 155.400(d) that a State Exchange must reconcile enrollment information with issuers and HHS no less than on a monthly basis. It also provides certainty for State Exchange issuers by providing a timeline for State

¹⁸³ CMS. (2024, Aug. 14). *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs)*. <https://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/downloads/faqs-sbe-reporting-enrollment-data-inaccuracies.pdf>.

¹⁸⁴ OMB Control No: 0938–1312 and 0938–1341.

Exchanges to act upon enrollment data inaccuracies submitted to the State Exchange by a State Exchange issuer that meets the requirements at § 156.1210(a)–(c).

Section 156.1210 generally requires State Exchange issuers to submit a description of all enrollment data inaccuracies, including those that impact APTC payments, to HHS or the State Exchange, as indicated by State Exchange guidance, in a manner and format specified by HHS or the State Exchange, within 90 calendar days of the date of a payment and collections report from HHS. At the same time, § 156.1210(b) also acknowledges that, in limited circumstances, HHS may consider inaccuracies received from a State Exchange issuer to resolve an enrollment data inaccuracy that was submitted after 90 calendar days when: (1) the State Exchange issuer notifies the State Exchange or HHS, as applicable, within 15 calendar days after identifying the inaccuracy; and (2) the State Exchange issuer's failure to identify the inaccuracy and submit to HHS or the State Exchange within the required 90 calendar day period was reasonable and not due to the issuer's misconduct or negligence.

Most recently, in the 2024 Payment Notice (88 FR 25886), we amended § 156.1210 to add paragraph (c), which provides a final deadline for issuers to submit data inaccuracies identified in payment and collections reports. Section 156.1210(c) specifies that to be eligible for resolution under § 156.1210(b), an issuer must describe inaccuracies before the end of the 3-year period beginning at the end of the plan year to which the inaccuracy relates. Notwithstanding the above, and in alignment with obligations under the False Claims Act,¹⁸⁵ issuers must report overpayments to HHS or the State Exchange and timely repay any overpayment, regardless of when a payment error is identified, including after the 3-year deadline.¹⁸⁶

Because State Exchanges provide the enrollment data that HHS uses as the basis of APTC payments to State Exchange issuers in the automated Policy-Based Payment (PBP) system, State Exchanges must update their enrollment data before HHS makes any PBP APTC payment adjustments to a State Exchange issuer. Therefore, the

State Exchange issuer must work with its State Exchange to ensure resolution of any inaccuracy impacting APTC payment. If a State Exchange issuer is directed by its State Exchange to submit inaccuracies directly to HHS, the State Exchange issuer should follow those submission instructions, but any information HHS shares in response to the submission is informational. If the inaccuracy remains unresolved, the State Exchange issuer must follow up with its State Exchange to identify and rectify the reason for non-resolution. In accordance with § 155.400(b), a State Exchange must submit all enrollment data that HHS then uses to calculate APTC payments to State Exchange issuers. Therefore, in instances when a State Exchange does not timely address State Exchange issuer data inaccuracies, HHS cannot directly assist the State Exchange issuer in addressing these data inaccuracies.

This proposal would codify guidance in the document titled, "Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges Frequently Asked Questions".¹⁸⁷ This guidance directs State Exchanges to review descriptions of data inaccuracies submitted by State Exchange issuers, resolve them, and submit to HHS a description of the resolution of the inaccuracies when the State Exchange issuer submits a description of a data inaccuracy within the 90 calendar day deadline, or reasonably after the 90 calendar day deadline but before the 3-year deadline pursuant to § 156.1210(b) and (c). The guidance directs State Exchanges to submit the resolution of these inaccuracies to HHS via the State Based Marketplace Inbound File (SBMI) within 60 calendar days after receiving from a State Exchange issuer a description of a data inaccuracy that includes all the information that the State Exchange requires or requests to properly assess the inaccuracy. This proposed timeline for resolution of enrollment data inaccuracies would require State Exchanges to timely review and resolve enrollment data inaccuracies; clarify the resolution process for State Exchange issuers; and ensure the accurate payment of APTCs, as enrollment data is the basis of APTC payments to State Exchange issuers in the automated PBP system. If this proposal is finalized, to track the State Exchanges' efforts to meet the 60-

calendar day requirement for submitting inaccuracies to HHS, we would consider modifying the State-based Marketplace Annual Reporting Tool (SMART) to have State Exchanges outline their processes for resolving data inaccuracies timely in accordance with this policy.

We solicit comments on this proposal.

5. Establishment of Optional Fixed-Dollar Premium Payment Threshold and Total Premium Threshold (§ 155.400(g))

We propose to codify a provision related to the premium payment threshold policies under § 155.400(g) that would allow additional issuer flexibility to decide when amounts collected from an enrollee would be considered to satisfy their obligation to pay the enrollee-responsible portion of the premium for certain purposes. Specifically, this would provide issuers with additional flexibility to not place an enrollee in a grace period for failure to pay the full amount of their portion of premiums due, and to not terminate enrollment through the Exchange after the applicable grace period ends without outstanding premiums being paid in full. This proposal would reduce the number of coverage terminations for enrollees who owe only a small amount of premium within the threshold. Specifically, we propose that issuers be permitted to set a fixed-dollar threshold of \$5 or less, which would be adjusted for inflation. We are also considering permitting issuers to adopt a threshold that is based on the gross premium owed by the enrollee, rather than net premium. We also propose to modify the threshold of the existing premium payment threshold policy at § 155.400(g) for clarity.

Currently, issuers have the option under § 155.400(g) to adopt a percentage-based premium payment threshold which allows issuers to effectuate coverage in accordance with binder payment rules at § 155.400(e) for enrollees who pay an amount of the enrollee-responsible portion of the premium that is less than 100 percent but within the threshold (we have historically recommended a percentage equal to or greater than 95 percent).¹⁸⁸ This avoids triggering a grace period for non-payment under § 156.270(d) or a grace period under State rules, and may avoid terminating enrollment for non-payment of premiums. Under this policy, if the total amount of premium owed by an enrollee (including aggregate amounts over multiple

¹⁸⁵ See 88 Fed Reg. 25740, 25887 ("Consistent with section 1313(a)(6) of the ACA and 31 U.S.C. 3729, *et seq.*, payments made by, through, or in connection with an Exchange are subject to the False Claims Act if those payment include any Federal funds").

¹⁸⁶ See 45 CFR 156.480 requiring State Exchange issues to maintain relevant records for 10 years.

¹⁸⁷ CMS. (2024, August 14). *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs)*. <https://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/downloads/faqs-SBE-reporting-enrollment-data-inaccuracies.pdf>.

¹⁸⁸ See CMS. (2023). *Federally-facilitated Exchange (FFE) Enrollment Manual*. Section 6.2. <https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf>.

months) exceeds the threshold set by the issuer, the issuer is required to place the enrollee in a grace period: either the grace period for enrollees receiving APTC described at § 156.270(d), or a grace period under State authority, as applicable. Any amount that is unpaid but within the reasonable premium payment threshold established by an issuer remains an amount owed by the enrollee and cannot be forgiven by the issuer.¹⁸⁹ Currently, this threshold must be a percentage, and it must be reasonable. We have stated that 95 percent or more of the enrollee-responsible portion of the premium would be a reasonable threshold.¹⁹⁰ This threshold must be applied uniformly to all enrollees.

In the 2017 Payment Notice (81 FR 12271 through 12272), in which HHS established the option for issuers to implement a percentage-based premium payment threshold, we received a comment requesting that issuers be allowed to establish a flat dollar amount threshold. At that time, we stated that we did not consider implementing such a threshold because there may be cases in which even a low flat dollar amount may represent a large percentage of an enrollee's portion of the premium less APTC (81 FR 12272).

However, after implementation of the percentage-based threshold, we have realized that the percentage-based premium threshold policy does not always adequately enable enrollees who owe small amounts of premium to avoid triggering a grace period or termination of enrollment through the Exchange. For example, an enrollee whose enrollee-responsible portion of the premium was \$1 after APTC, and who failed to make a premium payment, would be placed into a grace period even if the issuer had adopted a 95 percent payment threshold, despite being delinquent by only \$1. In an analysis of Exchange data for the 2023 Plan Year, we found that there were 81,383 total policies terminated for non-payment in which \$5 or less was owed by the enrollee, representing approximately 5.4 percent of the total number of policies terminated for non-payment that year. In addition, 102,728 policies in which enrollees owed premiums of \$5.01 to \$10 were terminated for non-payment, representing approximately 6.84 percent of the total number of policies terminated for non-payment. Even though \$5 may represent a large

percentage of an enrollee's portion of the premium less APTC, we believe that triggering a grace period or terminating enrollment through the Exchange is too severe a consequence for non-payment of such limited dollar amounts.

We are concerned about situations in which an issuer would be willing to avoid termination of enrollment through the Exchange if the enrollee owed only small amounts of premium but are prevented from doing so by the lack of flexibility in the current regulation. In addition, many of the enrollees who enter a grace period because they owe *de minimis* amounts of premium are likely low or moderate-income enrollees and thus might be especially hurt by disruptions in coverage. We recognize that issuers have historically implemented various premium payment thresholds, and we believe there is value in providing flexibility to issuers regarding whether to adopt a fixed-dollar payment threshold and the amount of the threshold.

We thus propose to modify § 155.400(g) to allow issuers to adopt a fixed-dollar premium payment threshold of \$5 or less, adjusted for inflation, under which they could provide additional flexibility to enrollees who fail to pay the full amount of their portion of premium owed. We propose to limit the fixed-dollar premium threshold to \$5 or less because, unlike the current percentage-based threshold, a fixed-dollar threshold would allow enrollees, in some cases, to pay \$0 in premium without the issuer triggering a grace period or terminating enrollment through the Exchange. Such a limit would ensure that enrollees who owe large amounts of premium do not remain enrolled in coverage through the Exchange and would serve to limit the number of times an enrollee may fail to pay premium and avoid triggering a grace period or termination of enrollment through the Exchange. We believe that a limit of \$5 is sufficiently large to enable issuers to allow enrollees who owe *de minimis* amounts of premium to remain enrolled, while ensuring that enrollees do not accumulate excessive amounts of premium owed prior to triggering a grace period or termination of enrollment through the Exchange. We recognize that this amount might be lower than the threshold enrollees might be afforded under a percentage-based threshold. However, we also recognize that within a percentage-based threshold, the enrollee must pay a certain amount of their premium to avoid triggering a grace period or termination of enrollment through the Exchange, whereas with a fixed-dollar

threshold, an enrollee may not have paid any other amount than the binder payment. Other factors such as the amount the enrollee has paid for their premium to date is not considered when applying the fixed-dollar payment threshold. We request comment on whether this is a reasonable limit for the fixed-dollar threshold, or whether an alternative amount (such as \$10) would be more appropriate and in line with our goal of enabling enrollees who owe small amounts of premiums, while avoiding excessive accumulation of premium debt, to avoid triggering a grace period or termination of enrollment through the Exchange. If adopted, we would publish updates through subregulatory guidance to this \$5 limit to adjust for inflation, using the National Health Expenditure Forecast published annually by CMS' Office of the Actuary.¹⁹¹

Issuers that adopt such a policy could permit enrollees who owe less than the specified amount of premium to avoid triggering a grace period and termination of enrollment through the Exchange. However, we propose to limit application of this threshold to premium payments made after coverage is effectuated, so that it could not apply to the binder payment. Issuers have the option under the current percentage threshold policy at § 155.400(g)(1) of applying a percentage-based threshold to the binder payment, but under that policy, enrollees are required to pay some amount of premium, even if it less than the total. By contrast, under a fixed-dollar premium payment threshold, enrollees could have their coverage effectuated without making any payment if their portion of the binder payment is under the threshold amount. Due to concerns about program integrity, we believe it is important to ensure that, when a binder payment is required, enrollees must always pay some amount of premium to effectuate coverage as an important signal that the coverage is desired by the enrollee. In addition, as under the current policy (81 FR 12272), any amount that is unpaid but within the reasonable premium payment threshold established by an issuer remains an amount owed by the enrollee and cannot be forgiven by the issuer. This remains true whether the premium payment threshold is utilized for any of the following payments: binder payments, regularly billed payments, or amounts owed by an enrollee while in a grace period.

¹⁸⁹ 2017 Payment Notice, 81 FR 12203, 12272.

¹⁹⁰ See CMS. (2023, July 12). *2023 Federally-facilitated Exchange (FFE) Enrollment Manual*. (Section 6.2, pp. 89–91). <https://www.cms.gov/files/document/jfe-enrollment-manual-2023-5cr-071323.pdf>.

¹⁹¹ See CMS. (n.d.). *National health expenditure data—Projected*. <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected>.

To illustrate how a fixed-dollar premium threshold will work under this proposal, we provide the following example:

Example 1: During the annual Open Enrollment Period, a consumer selects a QHP with a total monthly premium amount of \$300, and the consumer is determined eligible for \$299 in APTC and elects to receive the entire amount. The consumer's enrollee-responsible portion of premium will thus be \$1. The QHP issuer has adopted a fixed-dollar premium payment threshold policy under which it will not terminate enrollment of enrollees who owe \$5 or less of the enrollee-responsible portion of premium. The issuer has set a binder payment deadline of January 30, and the consumer sends the binder payment of \$1 ahead of the deadline and effectuates coverage effective January 1. Subsequently, the consumer does not make a payment for February, March, April, May, or June, and, as a result, the enrollee owes \$5 in outstanding premiums. Because the issuer has adopted a \$5 premium payment threshold, the issuer would not put the consumer into a grace period, since the total amount owed does not exceed \$5. However, the issuer would not be permitted to write off the \$5 owed, and if the consumer does not pay the premium for July in full, the issuer must put the consumer into a 3-month grace period since the total amount of premium owed would exceed the threshold set by the issuer. However, if within the grace period the consumer paid the full amount owed or a portion of the full amount owed that brings the amount owed under \$5, the issuer could terminate the grace period without terminating enrollment through the Exchange.

Finally, under the current percentage-based threshold policy, the percentage is calculated based on the percentage paid of the enrollee's portion of the premium (that is, the total premium minus any APTC). We are considering whether to further amend § 155.400(g) to also permit issuers to set a reasonable threshold that is a percentage of the policy's total premium and not just the enrollee's portion of premium, thus allowing APTC paid on the consumer's behalf to count toward the threshold.

In the 2017 Payment Notice (81 FR 12271 through 12272), we established the option for issuers to adopt a premium payment threshold based on net premium owed by the enrollee. At that time, we did not consider establishing a threshold based on gross premium, nor have we done so since then. We now recognize that this option may provide issuers with an alternative method of keeping consumers enrolled in coverage that issuers may prefer, either because it is simpler to implement or because it is percentage-based and therefore more similar to the premium payment threshold that is currently allowed under § 155.400(g).

Establishing an option for issuers to adopt a percentage threshold based on gross premium owed by the enrollee with APTC counting toward the threshold would, in some cases, allow enrollees to remain enrolled in coverage or avoid triggering a grace period or termination of enrollment through the Exchange for owing small amounts of the enrollee-responsible portion of the premium. For example, an enrollee whose gross premium was \$600, and was receiving \$595 in APTC, could avoid triggering a grace period or termination of enrollment through the Exchange or termination of coverage even without paying the \$5 enrollee-responsible portion of the premium if the issuer had adopted a 99 percent premium threshold based on gross premium because 99 percent of the gross premium would have been paid on the enrollee's behalf in the form of APTC. With the current 95 percent threshold based on net premium, by contrast, the enrollee would be required to pay at least \$4.75 to avoid triggering a grace period or termination of enrollment through the Exchange. While historically we have not defined a specific threshold for the premium threshold based on net premium, we would implement a threshold for the premium threshold based on gross premium that is 99 percent or more of the gross premium. We believe the gross premium threshold should be higher than the net premium threshold to avoid the enrollee accumulating a much larger amount of premium debt, and to keep to a similar *de minimis* amount of premium owed as the net premium percentage-based and fixed-dollar thresholds allow. Because this threshold would also, in some circumstances, allow enrollees to temporarily avoid paying any premium, we would also propose to limit application of this threshold to premium payments made after coverage is effectuated, so that it could not apply to the binder payment (due to operational and program integrity concerns, as discussed earlier in this section).

A percentage threshold based on gross premium may be simpler to implement, since it is similar to the type of threshold issuers are already allowed to adopt. However, we recognize that there may also be drawbacks to this approach, including that enrollees could accumulate more than \$5 in premium debt, which the enrollee would continue to owe even if coverage were eventually terminated due to non-payment of premiums. Based on our experience with the current, net premium-based payment threshold, we

do not believe this would result in significant premium debts accumulated by enrollees, since we are limiting the gross percentage-based threshold to be 99 percent or more of the gross premium. We recognize that a gross premium amount higher than the average gross premium (which was \$604.78 in February 2023)¹⁹² might allow enrollees to accrue more than the \$5 debt that could be accrued under the fixed-dollar threshold, but this is true under the existing net premium payment threshold as well. We also note that issuers are prohibited from attributing premiums owed to prior debts and not to binder payments, and thus issuers may not refuse to enroll enrollees in coverage based on failure to pay their binder payment by attributing binder payments to prior debts.

To illustrate how a premium threshold based on gross premium would work under this proposal, we provide the following example:

Example 2: During the annual Open Enrollment Period, a consumer selects a QHP with a total monthly premium amount of \$500, and the consumer is determined eligible for \$495 in APTC and elects to receive the entire amount. The consumer's enrollee-responsible portion of premium will thus be \$5. The QHP issuer has adopted a percentage-based premium payment threshold policy under which it will not trigger a grace period or termination of enrollment through the Exchange for enrollees who pay at least 99 percent of gross premium (including payments of APTC made on the enrollee's behalf), which here would be \$5. The issuer has set a binder payment deadline of January 30, and the consumer sends the binder payment of \$5 ahead of the deadline and effectuates coverage effective January 1. Subsequently, the consumer pays \$1 in February and owes \$4 in past due premium; because the consumer's payment is within the 99 percent threshold established by the issuer, the issuer would not place the enrollee in a grace period. The following month, the consumer does not pay any premium, and now owes \$9 in past due premium. Since the \$9 now owed after application of the \$495 APTC paid on the consumer's behalf for March represents more than 1 percent of the \$500 gross premium, the issuer must put the consumer into a 3-month grace period starting March 1. The issuer would not be permitted to write off the \$9 owed, and the consumer must pay all outstanding premium owed before the end of the grace period (May 31) to avoid exhaustion of the grace period and remain enrolled in coverage.

We seek comments on this proposal. Specifically, we request comment on whether a fixed-dollar threshold, as

¹⁹² See CMS (2024) *Effectuated Enrollment: Early 2024 Snapshot and Full Year 2023 Average*. <https://www.cms.gov/files/document/early-2024-and-full-year-2023-effectuated-enrollment-report.pdf>.

proposed, or a percentage threshold based on gross premium, would better meet our goal of providing flexibility to issuers to allow enrollees to avoid triggering a grace period or termination of enrollment through the Exchange for owing small amounts of premium.

We also propose changing the premium payment threshold based on net premium owed by the enrollee from being a “reasonable” standard to a specifically defined threshold of 95% or higher of the net premium. We believe this would provide clarity for issuers and Exchanges.

We also propose limiting issuers to utilize one premium payment threshold, such that a fixed-dollar threshold cannot be adopted and utilized in tandem with a percentage-based policy, either net or gross. We believe that limiting this flexibility would allow issuers to choose and apply the threshold that works best for their payment operations but prevents complex situations that may arise from allowing multiple thresholds to be used simultaneously. We seek comment on whether we should allow issuers to adopt both a fixed-dollar and percentage-based threshold, and request commenters to consider the administrative feasibility of applying both thresholds, and how such a policy could be applied uniformly and consistently across enrollees.

6. General Eligibility Appeals Requirements (§ 155.505)

We propose revising § 155.505(b) to codify an option for application filers to file appeals on behalf of applicants and enrollees on the application filer’s Exchange application.

The Exchanges on the Federal platform allow application filers as defined under § 155.20 to file applications on behalf of an applicant. However, the appeals regulation at § 155.505(b) states that only applicants and enrollees may submit appeal requests to the HHS appeals entity or a State Exchange appeals entity. Appeal requests submitted online to the HHS appeals entity are linked to a consumer’s *HealthCare.gov* account, which is controlled by the application filer. Thus, an application filer who has authority to apply for coverage through *HealthCare.gov* on behalf of an applicant under § 155.20, does not have parallel authority under § 155.505(b) to appeal a contested eligibility determination on behalf of that applicant through the same *HealthCare.gov* account.

This limitation under § 155.505(b) puts a burden on consumers, as appeals filed by application filers who are

neither an applicant or enrollee are considered invalid based on lack of standing, requiring either that the applicant or enrollee resubmit their appeal or that they designate the application filer as an authorized representative in writing. These extra steps not only add unnecessary complications for the applicant or enrollee, but also serve to delay an appeal resolution that may grant or restore QHP coverage and financial assistance.

This proposed change would allow application filers to file appeals through the HHS appeals entity or a State Exchange appeals entity on behalf of applicants and enrollees on their Exchange application, streamlining the appeals process and ensuring operational consistency throughout the application and appeals processes. We do not anticipate that this would impose any additional substantial burden on any Exchanges, including State Exchanges that operate their own platform, as this should not materially increase the number of appeals filed, or add complexity to appeals processes.

We seek comment on this proposal.

7. Certification Standards for QHPs (§ 155.1000)

We propose to amend § 155.1000 by adding a new paragraph (e) stating that an Exchange may deny certification of any health plan as a QHP that does not meet the general certification criteria at § 155.1000(c).

Section 1311(e)(1) of the ACA grants an Exchange the authority to certify a health plan as a QHP if the health plan meets the requirements for certification promulgated by the Secretary under section 1311(c)(1) 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.¹⁹³ In the Exchange Establishment Rule (77 FR 18310, 18404 through 18405), we codified the responsibilities of an Exchange to certify QHPs at § 155.1000, and under § 155.1000(b), required Exchanges to only offer health plans which have in effect a certification issued or are recognized as health plans deemed certified for participation in an Exchange as a QHP. In that final rule, we also codified general certification

criteria, consistent with sections 1311(e)(1)(A) and (B) of the ACA, at § 155.1000(c): an Exchange may certify a plan as a QHP if: (1) the health insurance issuer provides evidence during the certification process that it complies with the applicable minimum certification requirements outlined in subpart C, part 156 of our regulations; and (2) the Exchange determines that making the health plan available through the Exchange is in the interest of qualified individuals and qualified employers.¹⁹⁴

However, an Exchange’s authority to deny certification is not explicitly referenced in 45 CFR part 155. Several regulations, including §§ 155.1000(c) and 155.1090, can be read to imply, but do not explicitly state, that an Exchange may deny certification of a health plan that does not meet the requirements of § 155.1000(c). Despite this omission from our regulations, a plain reading of section 1311(e)(1) of the ACA makes clear that an Exchange, as the entity statutorily responsible for determining whether a plan meets the minimum QHP certification standards, has the implied authority to deny certification of plans that do not meet these standards. Any contrary read of section 1311(e)(1) of the ACA would mean that an Exchange does not have any statutory authority to take any action for plans that do not meet minimum certification standards, which is not a reasonable result.

We seek to revise our regulations so that they more fully and accurately reflect the discretion that Exchanges have to deny certification of any plan that does not meet the general certification criteria at § 155.1000(c). Accordingly, we propose to use the authorities under section 1311(c) of the ACA (which gives HHS the authority to establish criteria for the certification of health plans as QHPs), section 1311(d)(4)(A) (which provides that Exchanges shall implement procedures for the certification, recertification, and decertification of QHPs consistent with the guidelines HHS develops under section 1311(c)), and section 1321(a)(1)(B) (which provides HHS with broad rulemaking authority to issue regulations setting standards for meeting the requirements under title I of the ACA (which includes section 1311) for the establishment and operation of Exchanges and the offering of QHPs through the Exchanges) to add new paragraph (e) to § 155.1000 to formalize

¹⁹³ Section 1311(c)(1)(B) of the ACA and § 155.1000(c)(2) further provide that an Exchange may not exclude a health plan (i) on the basis that such plan is a fee-for-service plan, (ii) through the imposition of premium price controls, or (iii) on the basis that the plan provides treatments necessary to prevent patients’ deaths in circumstances the Exchange determines are inappropriate or too costly.

¹⁹⁴ In that rule, we outlined a number of non-exhaustive strategies an Exchange may employ to determine whether the offering of a health plan is in the interest of qualified individuals and qualified employers (77 FR 18406).

the implicit authority that an Exchange, including State Exchanges and SBE-FPs, may deny certification to any plan that does not meet the general certification criteria at § 155.1000(c). Under this proposal, an Exchange may deny certification if the issuer does not provide evidence during the certification process in § 155.1010 that it complies with the minimum certification requirements (under § 155.1000(c)(1)), or if the Exchange determines that making the health plan available is not in the interest of the qualified individuals and qualified employers (under § 155.1000(c)(2)).

To be clear, we are not proposing to require Exchanges, including State Exchanges and SBE-FPs, to implement any specific procedures or processes for the denial of a QHP certification application. This proposal is not intended to amend the existing, implied authority of an Exchange to deny certification. This proposal is only intended to make that authority more explicit in our regulations, which will provide greater certainty to Exchanges, issuers, and consumers on an Exchange's role, which we expect will only improve the efficiency of the Exchanges.

We seek comment on this proposal.

8. Request for the Reconsideration of Denial of Certification Specific to the FFEs (§ 155.1090)

We propose to amend § 155.1090 to revise the standards for an issuer to request the reconsideration of denial of certification as a QHP specific to the FFEs.

Section 1311(e)(1) of the ACA grants an Exchange the authority to certify a health plan as a QHP if the health plan meets the requirements for certification promulgated by the Secretary under section 1311(c)(1) 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.¹⁹⁵ In the 2018 Payment Notice (81 FR 94137), we finalized § 155.1090 to allow an issuer to request the reconsideration of a denial of certification of a plan as a QHP for sale through an FFE.

HHS, as operator of the FFEs, is responsible for ensuring that health plans offered through the FFEs meet all

Federal requirements for certification as QHPs under § 155.1000(c). Starting with the 2014 plan year, HHS has certified numerous health plans as QHPs on the FFEs. During this time, HHS has also determined that a small number of applications submitted by issuers for the certification of health plans as QHPs on the FFEs did not meet minimum certification criteria under § 155.1000(c), and HHS denied certification to these plans. Some of these issuers submitted reconsideration requests to HHS under § 155.1090(a)(1). HHS ultimately sustained its denial determinations for these issuers' certification applications upon reconsideration review.

Based on our experience reviewing these certification application reconsideration requests, we believe that it would be appropriate to amend § 155.1090 to codify more structure for the FFEs' process for conducting a reconsideration of denial of certification. Accordingly, we propose to use the authorities under section 1311(c) of the ACA (which gives HHS the authority to establish criteria for the certification of health plans as QHPs), section 1311(d)(4)(A) (which provides that Exchanges shall implement procedures for the certification, recertification, and decertification of QHPs consistent with the guidelines HHS develops under section 1311(c)), and section 1321(a)(1)(B) (which provides HHS with broad rulemaking authority to issue regulations setting standards for meeting the requirements under title I of the ACA (which includes section 1311) for the establishment and operation of Exchanges and the offering of QHPs through the Exchanges) to require that an issuer's reconsideration request meet a specified burden of proof. Specifically, we propose revising § 155.1090(a)(2) to state that the burden is on an issuer that is denied certification to provide evidence that HHS' determination that the plan does not meet the certification criteria at § 155.1000(c) was in error.

As we stated in the Exchange Establishment Rule (76 FR 41891), offering only QHPs through an Exchange assures consumers that the coverage options presented through the Exchange meet certain minimum Federal standards. Given the voluntary nature of QHP certification, the FFEs utilize a process for QHP certification whereby the burden of proof is on issuers to provide sufficient evidence that they comply with those minimum Federal standards to obtain

certification.¹⁹⁶ Consistent with this general approach towards QHP certification, we believe it is appropriate to propose formalizing that the burden of proof involved in a reconsideration request is also on issuers. Under this proposal, an issuer that is denied certification on an FFE would be responsible for submitting a request to HHS, as operator of the FFEs, for reconsideration of a denial determination.

We also propose to revise § 155.1090(a)(2) to require that, as part of a reconsideration request, an issuer would be required to submit clear and convincing evidence that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error. We explained in the 2017 Payment Notice (81 FR 12289) that HHS expects to certify the vast majority of plans that meet the certification standards. To maximize this amount of time for health plans to prepare, submit, and revise QHP applications to the FFEs, HHS provides as much time as it can for issuers to demonstrate that they comply with the certification standards. The FFE's QHP certification timeline provides at least three opportunities for issuers to submit application materials to demonstrate that it meets minimum certification standards for a given plan year (four opportunities, if the issuer avails itself of an optional early bird submission). As such, by the time it issues a denial of certification, HHS will have typically already received substantial factual information from the issuer over the period of several months upon which it will have based its denial determination. It is unlikely that any additional evidence that the issuer would seek to provide upon reconsideration request that they had not already provided during the three or four rounds of application submissions would meaningfully weigh in favor of certification unless it clearly and convincingly establishes that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error.

Under this proposal, we would expect evidence to be clear and convincing that HHS' determination was in error if the issuer demonstrates that HHS clearly misunderstood or misinterpreted facts or data already provided by the issuer in previously submitted application materials (such as network adequacy calculation errors). We would not

¹⁹⁵ Section 1311(c)(1)(B) of the ACA and § 155.1000(c)(2) further provide that an Exchange may not exclude a health plan (i) on the basis that such plan is a fee-for-service plan, (ii) through the imposition of premium price controls, or (iii) on the basis that the plan provides treatments necessary to prevent patients' deaths in circumstances the Exchange determines are inappropriate or too costly.

¹⁹⁶ See § 155.1000(c)(1): "The health insurance issuer provides evidence during the certification process in § 155.1010 that it complies with the minimum certification requirements outlined in subpart C of part 156, as applicable."

expect evidence to be clear and convincing in this regard if it is substantially based on new information (such as the inclusion of new ECPs that the issuer did not include in previously submitted application materials) or is comprised of disputes of HHS' authority to ensure compliance with certification standards (such as a determination that making the plan available is not in the interest of the qualified individuals and qualified employers, under section 1311(e)(1)(B) of the ACA and § 155.1000(c)(2)) that would require HHS to perform de novo analysis before open enrollment.

Finally, we propose to revise the title of § 155.1090 to state, "Request for the reconsideration of a denial of certification" and the subtitle of § 155.1090(a) to state, "Request for the reconsideration of a denial of certification specific to a Federally-facilitated Exchange."

We seek comment on this proposal.

9. General Program Integrity and Oversight Requirements (§ 155.1200)

We currently collect certain information and data from State Exchanges and SBE-FPs under § 155.1200 to monitor their performance and compliance. Under our authority under section 1321(a)(1)(D) of the ACA to promulgate appropriate requirements related to Exchanges, we are proposing to also use this information and data to increase transparency into State Exchange operations and to promote program improvements.

Under § 155.1200, State Exchanges must report to HHS on certain Exchange-related activities and performance monitoring data. State Exchanges must also engage an independent qualified auditing entity which follows generally accepted government auditing standards (GAGAS) to annually compile a financial statement and conduct a financial audit and a programmatic audit.

To meet these requirements, under section 1313(a)(1) of the ACA, State Exchanges and SBE-FPs are required to submit a State Marketplace Annual Reporting Tool (SMART) to CMS, which CMS uses to monitor and evaluate State Exchange compliance with Exchange requirements under Title I of the ACA.¹⁹⁷ Through the SMART, State Exchanges and SBE-FPs attest to compliance with specific regulations, provide supporting documentation

including, if applicable, a redetermination plan for the upcoming plan year, an oversight and monitoring plan with fraud, waste, and abuse policies and procedures, nondiscrimination policies and standards, and an operating budget with a financial statement. Additionally, the Exchanges submit the financial and programmatic audits with corrective action plans for any identified audit or findings. Following review, we provide State Exchanges and SBE-FPs with a SMART summary letter based on the observations and action items identified and monitor State Exchange completion of any open findings.

State Exchanges that operate their own eligibility and enrollment platform also report enrollment and Exchange activity data to CMS weekly during Open Enrollment and twice a year outside of Open Enrollment.¹⁹⁸ We publish Exchange Open Enrollment data annually.¹⁹⁹ We utilize the programmatic data received from State Exchanges to identify program risks and provide technical assistance to State Exchanges on corrective actions or strategies to mitigate risks, as well as to inform the development of new or updated policies as part of our annual rule-making processes to address known risks.

In the 2025 Payment Notice (89 FR 26218), we noted that in the interest of transparency, we are considering the development of new tools to provide further information to the public about the performance of Exchanges. We are now proposing that, in addition to collecting the information and data currently submitted to CMS by State Exchanges and SBE-FPs under § 155.1200 to monitor performance and compliance, we would use the information and data to increase transparency into State Exchange operations and to promote program improvements. We would value feedback on our proposed approaches to meeting this objective.

Specifically, we plan to publicly release the State Exchange and SBE-FP annual SMARTs and financial and programmatic audits in addition to any documentation of corrective actions or open findings. We believe that in addition to increasing the public's understanding of State Exchanges, the release of the SMARTs and related documents, including programmatic

and financial audits, would help ensure that the SMART and State Exchange compliance activities are conducted in a more transparent manner. Our intention is to begin with publication of the Plan Year 2023 SMART (which was due from the State Exchanges and SBE-FPs to CMS on June 1, 2024, and are currently under compliance review) beginning Spring 2025.

We also intend to expand on current Open Enrollment data reporting by publishing additional metrics on State Exchange operations and functionality that we currently collect from State Exchanges, but do not currently report to external audiences. This data includes State Exchange spending on outreach (including Navigators), eligibility and enrollment policies and processes, plan certification requirements, and operational performance data, including Open Enrollment call center metrics (call center volume, average wait time, average call abandonment rate) and website visits and visitors. We believe that increasing transparency would allow the public to better understand the performance of the Exchanges, and it is our intention that this public reporting of State Exchange operations and functionality would include public release of comparable metrics for the FFEs and SBE-FPs.

We are interested in comments as to what other Exchange metrics would be useful to disclose to the public.

D. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. Solicitation of Comments—Reducing the Risk That Issuer Insolvencies Pose to the Integrity of the Federally-Facilitated Exchanges

Several instances of issuer insolvencies (each involving multi-State parent organizations with several subsidiaries) have in recent years destabilized certain State markets and caused significant disruption to consumers, including in the applicable Exchanges. The disruptive nature of these incidents prompted State Departments of Insurance (DOIs), trade organizations, and issuers to request that we intervene to restabilize affected markets and employ additional measures to reduce the risk of similar scenarios occurring in subsequent years. In response to this feedback, we are soliciting comments on methods that HHS, as operator of the FFEs, could potentially employ, in partnership with State regulators, to reduce the risk that

¹⁹⁷ OMB. *State-based Marketplace Annual Reporting Tool (SMART)*. OMB control number: 0938-1244. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/smart_2017_5.pdf.

¹⁹⁸ OMB control number: 0938-1119.

¹⁹⁹ See, for example, CMS. (2024, March 22). *2024 Marketplace Open Enrollment Period Public Use Files*. <https://www.cms.gov/data-research/statistics-trends-reports/marketplace-products/2024-marketplace-open-enrollment-period-public-use-files>.

issuer insolvencies pose to the integrity of the FFEs.

One example of a potential approach we are considering adopting, and therefore solicit comment on, could be to increase our coordination with State DOIs, individually and collectively in the case of multi-State issuers, and the National Association of Insurance Commissioners (NAIC). Under this approach, we could review QHP applications in FFE States to identify issuers that are at risk of experiencing solvency-related difficulties, both at the time of an issuer's application for QHP certification and on a rolling basis throughout the plan year. To assess issuer solvency, we could examine well-understood and industry-standard financial measures, such as the risk-based capital ratio and quick ratio, in partnership with State regulators.

The risk-based capital ratio is an industry-standard regulatory method used to determine the minimum amount of capital an issuer must maintain to cover its risk. The risk-based capital ratio an issuer must maintain (in accordance with State licensure requirements) is based on the inherent level of risk associated with its financial assets, insurance products, and business operations. The risk-based capital ratio is defined as the ratio of an issuer's total adjusted capital to its authorized control level risk-based capital. Total adjusted capital is typically cash or liquid assets being held or obtained for expenditures. Authorized control level risk-based capital, also referred to as risk-weighted assets, is the denominator in the risk-based capital ratio. Authorized control level risk-based capital is used to determine the minimum amount of capital an issuer must hold in relation to the risk profile of its activities and other assets.²⁰⁰

A low risk-based capital ratio may indicate that an issuer is insufficiently capitalized and therefore may be unable to pay claims and risk adjustment charges in a longer time horizon. Thus, monitoring issuers' risk-based capital ratios enables regulators to identify potentially insufficiently capitalized issuers, which could facilitate necessary regulatory intervention to ensure enrollees receive benefits without relying on a guaranty association or taxpayer funds. In the context of the Exchanges, such regulatory intervention could include implementing plan suppressions, enrollment caps, denying

QHP certification, or decertifying existing QHPs.

While the risk-based capital ratio provides a measure of an issuer's overall long-term financial viability, it does not so readily indicate whether an issuer is able to pay claims or risk adjustment charges in the more immediate term by quickly liquidating its assets. For example, an issuer could have a risk-based capital ratio indicating a sufficient degree of capitalization but may not be able to quickly liquidate its assets to cover its immediate liabilities, either in the form of claims or risk adjustment payments.

As such, we are interested in comments on whether we should consider also utilizing a second industry-standard measure of financial instability, the quick ratio, which is a type of liquidity ratio, to assess issuer solvency. The quick ratio measures an issuer's ability to use its near-cash or "quick" assets to extinguish or retire its current liabilities immediately. The quick ratio is defined as the ratio between quickly available or liquid assets and current liabilities.²⁰¹ Quick assets are current assets that can presumably be quickly converted to cash at close to their book values. Possessing sufficient quick assets ensures issuers are able to timely cover all claims in a more immediate timeframe.

The quick ratio is a more conservative estimate of how liquid a company is compared to other calculations that include potentially illiquid assets, such as the risk-based capital ratio. In particular, the quick ratio addresses an issuer's ability to pay outstanding debts. This financial metric alone does not provide any indication about a company's future cash flow activity. However, the utilization of the quick ratio, in conjunction with the risk-based capital ratio, could potentially facilitate the identification of issuers with potential financial viability concerns that may pose risk to the integrity of the FFEs.

Altogether, monitoring issuers' risk-based capital ratios could facilitate the assessment of an issuer's longer-term prospects for financial viability, while monitoring issuers' quick ratios could facilitate the assessment of issuers' more immediate term prospects for financial viability. Together, the utilization of these two complementary measures could potentially provide a more holistic view of issuers' financial viability and help HHS, as operator of

the FFEs, in partnership with applicable State DOIs, take the action necessary to ensure the integrity of the FFEs (such as by suppressing QHPs under § 156.815, instituting enrollment caps—which have been previously operationalized by implementing QHP suppressions under § 156.815(b)(5) based on the guaranteed availability exceptions at § 147.104(c) and (d), denying QHP certification applications under § 155.1000(c), or decertifying QHPs under § 156.810).

Under this potential approach, HHS, in partnership with State regulators, could assess an issuer's financial stability based on its risk-based capital ratio and its quick ratio using data that is included in the statutory annual and quarterly financial statements that issuers are already required to file with the NAIC. Since these materials are already available to HHS, this approach would not require issuers to prepare and submit additional materials to HHS, which would minimize burden on QHP issuers.

In addition to monitoring issuers' risk-based capital ratios and quick ratios to identify issuers at risk of experiencing solvency-related difficulties, HHS could work in partnership with applicable State regulators to identify issuers that are experiencing levels of enrollment growth that risk exceeding their capitalization rates, which has historically tended to occur in large part due to the relative premium position of issuers' newly-offered plans (specifically, having the lowest-cost bronze or silver plan in the county).

Issuers experiencing enrollment growth disproportionately comprised of comparatively low-risk enrollees that exceeds their capitalization rates has been a primary contributing factor in each of the recent instances of issuer insolvencies. In particular, in these instances of issuer insolvencies, insufficiently capitalized issuers underpriced their QHPs, which attracted a high number of relatively low-risk enrollees. These issuers subsequently accrued significantly higher-than-anticipated risk adjustment charges due to the relatively low risk profiles of their enrollees, which in turn led to these issuers being unable to timely pay risk adjustment charges in full.

Upon identifying issuers with insufficient risk-based capital and quick ratios, and/or issuers with enrollment growth that risks exceeding their capitalization rates, HHS could engage applicable State regulators—including State regulators in the affected States, regulators of those issuers in their States of domicile, and regulators of affiliated

²⁰⁰ National Association of Insurance Commissioners. (2024, Jan. 1). *Risk-Based Capital*. <https://content.naic.org/cipr-topics/risk-based-capital>.

²⁰¹ Corporate Finance Institute. (n.d.) *Quick Ratio*. <https://corporatefinanceinstitute.com/resources/accounting/quick-ratio-definition/>.

entities within the same parent organization domiciled in other States. HHS and those State regulators could then discuss the advisability of having these plans certified to be offered on their respective Exchanges. Discussions with State regulators could include whether those States should request that HHS invoke the exceptions to guaranteed availability for financial capacity under § 147.104(d), and whether States should request that HHS institute a temporary enrollment cap if an issuer demonstrates an insufficient risk-based capital ratio and/or quick ratio, or if an issuer experiences enrollment growth that risks exceeding its capitalization rate.

Under this potential approach, we could monitor issuers offering QHPs through the FFEs—but not issuers only offering QHPs through State Exchanges or SBE-FPs. This is because we believe that State Exchanges (including SBE-FPs) are best positioned to understand both the nuances of their respective markets and the specific needs of qualified individuals enrolling in QHPs. We also believe that States that have invested the necessary time and resources to establish State Exchanges have done so to implement policies that differ from those on the FFEs, and we do not wish to impede these efforts, so long as they comply with existing legal requirements. However, we believe that HHS can serve a useful role in identifying broader risks that span multiple markets by convening States that regulate multi-State issuers.

State regulators are the primary regulators of licensure requirements, including solvency. Indeed, we strongly believe that States are best positioned to exercise these responsibilities as a general matter. Since HHS, as the operator of the FFEs in many States and as the operator of risk adjustment in all States, has a more complete view of multi-State issuers, and, in FFE States, the ability to wield Exchange-specific tools (such as plan suppressions, enrollment caps, denial of QHP certification applications, and the decertification of existing QHPs), we believe HHS can serve a useful role in promoting thoughtful discussions with and among State regulators around the advisability of certifying plans where there may be concerns around capitalization and enrollment growth that risks exceeding capitalization rates. Regardless, we underscore that nothing in this or any other potential approach we are considering would preempt any State's licensing requirements with regard to solvency or financial matters.

We solicit comments on this and other potential approaches for reducing

the risk that issuer insolvencies pose to the integrity of the FFEs.

2. FFE and SBE-FP User Fee Rates for the 2026 Benefit Year (§ 156.50)

For the 2026 benefit year, we propose an FFE user fee rate of 2.5 percent of total monthly premiums and an SBE-FP user fee rate of 2.0 percent of total monthly premiums. These significant increases in the FFE and SBE-FP user fee rates would be necessary if Congress does not act to extend enhanced PTC subsidies²⁰² into 2026. In the absence of Congressional action, we project large decreases in enrollment for 2026, requiring us to reverse the reductions in the FFE and SBE-FP user fee rates that were made possible by record-setting enrollment in recent years.

However, Congressional action that extends the enhanced PTC subsidies under the IRA through the 2026 benefit year, prior to issuer rate-setting deadlines for the 2026 benefit year, would lead us to revise our enrollment projections and modify the FFE and SBE-FP user fee rates to rates closer to FFE and SBE-FP user fee rates for 2025 than the proposed rates. Specifically, if the enhanced PTC subsidies as currently enacted²⁰³ or at a higher level are extended through the 2026 benefit year by March 31, 2025, we propose a 2026 benefit year FFE user fee rate range between 1.8 and 2.2 percent of total monthly premiums and a 2026 benefit year SBE-FP user fee rate range between 1.4 and 1.8 of total monthly premiums, with each of these ranges to be set at a single rate in the final rule. These ranges are based in part on projected enrollment during the 2025 open enrollment period. HHS will have a better understanding of the projected open enrollment numbers to finalize a single FFE and SBE-FP user fee rate within those ranges in the final rule (as more data about the 2025 open enrollment period will be available for calculating a single FFE and SBE-FP user fee rate for the final rule). In finalizing a single FFE and SBE-FP user fee rate within the proposed range, we would also consider any changes to our premium estimates or budget based on the most recently available data.

HHS also notes that this same dynamic related to lower enrollment is present across numerous calculations HHS makes associated with operation of the Exchange, outside the context of this proposed rule. For example, a reduction in enhanced PTC subsidies may

considerably impact pass-through funding to States for programs established under Section 1332 waivers. Similarly, the expiration of enhanced PTC subsidies may affect BHP States' ability to implement, sustain, and expand their BHP programs. Lastly, we note that increased enrollment due to enhanced PTC subsidies has increased overall projected enrollment. In the absence of Congressional action to extend enhanced PTC subsidies, those calculations and payments will assume lower enrollment and lower APTC and PTC levels.

We are proposing March 31, 2025 as the date by which enhanced PTC subsidies must be extended in order for HHS to apply the alternative FFE and SBE user rates, because we anticipate this date as the latest date we could select that would still provide issuers the opportunity to take enactment of the law into account in setting rates for the 2026 benefit year and for HHS or States, as applicable, to timely review and approve those rates. However, we seek comment on whether March 31, 2025 provides sufficient time and whether we should select an earlier or later date.

Section 1311(d)(5)(A) of the ACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a State does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the ACA directs HHS to operate an Exchange within the State. Accordingly, in § 156.50(c), we state that a participating issuer offering a plan through an FFE or SBE-FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE-FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE-FP. OMB Circular A-25 established Federal policy regarding user fees and what the fees can be used for.²⁰⁴ OMB Circular A-25 provides that a user fee charge will be assessed against each identifiable recipient of special benefits derived from Federal activities beyond those received by the general public.

a. FFE User Fee Rates for the 2026 Benefit Year

Section 156.50(c)(1) provides that, to support the functions of FFEs, an issuer

²⁰² ARP, Public Law 117-2 (2021). These enhanced subsidies were extended under the IRA, Public Law 117-169 (2022) and are scheduled to expire after the 2025 calendar year.

²⁰³ Ibid.

²⁰⁴ See OMB. (n.d.) Circular No. A-25 Revised. <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>.

offering a plan through an FFE must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE. As in benefit years 2014 through 2025, issuers seeking to participate in an FFE in the 2026 benefit year will receive two special benefits not available to issuers offering plans in State Exchanges: (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 2026 benefit year, issuers participating in an FFE will receive special benefits from the following Federal activities:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Enrollment processes; and
- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification).

Activities performed by the Federal government that do not provide issuers participating in an FFE with a special benefit are not covered by the FFE user fee.

The proposed user fee rate reflects our estimates for the 2026 benefit year of costs for operating the FFEs, premiums, enrollment, and transitions in Exchange models from the FFE and SBE–FP models to either the SBE–FP or State Exchange models. The total enrollment in Exchanges in States anticipated to transition from operating an SBE–FP to a State Exchange model represents premiums for which we will no longer collect user fees, and the total enrollment in Exchanges in States anticipated to transition from an FFE to an SBE–FP model represents premiums for which we will assess user fees at the lower SBE–FP rate. Thus, these anticipated transitions impact our total projected collections and may affect the FFE and SBE–FP user fee rates and are considered as part of our calculation of our proposed user fee rates.

To develop the proposed 2026 benefit year FFE user fee rates, we considered a range of costs, premiums, and enrollment projections.²⁰⁵ For the

proposed 2026 benefit year user fee rates, we estimated that contract and labor costs would increase from the 2025 benefit year. Particularly, we have experienced increases in costs related to regulation of agents and brokers, consumer outreach and education, eligibility determinations, enrollment processes, and certification processes for QHPs.

We took several factors into consideration in choosing which premium and enrollment projections would inform the proposed 2026 FFE user fee rates. First, for our estimated premium trend rate projections, we found based on our analysis of historical premium trend data that our actual average premium trend rate was lower than we had estimated in prior benefit years and therefore, for our projected 2026 benefit year user fee rates, we decreased our estimated premium trend rate projections. This change serves to better align with our historical premium trend experience, and to reflect that the total monthly premiums to which the proposed FFE and SBE–FP user fee rates would be applied are likely to be lower than previously expected.

For the 2021 through 2025 benefit years, we projected increased enrollment in the individual non-catastrophic market risk pool in most States, due to the enhanced PTC subsidies provided for in the ARP²⁰⁶ 207 and the extension of the PTC subsidies through the 2025 benefit year under section 12001 of the IRA.²⁰⁸ Our 2026 enrollment estimates account for the projected transitions of States from FFEs or SBE–FPs to State Exchanges, the enrollment impacts of section 1332 waivers, and transitioning Medicaid Expansion States. We also carefully considered the impact of the expiration of the enhanced PTC subsidies on 2026 benefit year Exchange enrollment in the individual market.

We believe that the 2026 benefit year is uniquely uncertain due to the potential significant changes in enrollment expected if the enhanced PTC subsidies expire at the end of the 2025 benefit year under current law. We understand that many interested

have in prior rulemakings, our own internal data. See, for example, 88 FR 25845; see also, Congressional Budget Office. (2024, June 18). *Health Insurance Coverage for the US Population, 2024 to 2034*. <https://www.cbo.gov/system/files/2024-06/60040-Health.pdf>.

²⁰⁶ ARP, Public Law 117–2 (2021).

²⁰⁷ CMS. (2023). *Summary Report on Permanent Risk Adjustment Transfers for the 2022 Benefit Year*. (p. 8). <https://www.cms.gov/files/document/summary-report-permanent-risk-adjustment-transfers-2022-benefit-year.pdf>.

²⁰⁸ Inflation Reduction Act, Public Law 1217–169 (2022).

parties²⁰⁹ have expressed interest in permanently extending the enhanced PTC subsidies established in section 9661 of the ARP and extended in section 12001 of the IRA beyond the 2025 benefit year. We recognize that the expiration of the subsidies at the end of the 2025 benefit year creates a significant amount of uncertainty in the ACA markets and their expiration will have a ripple impact across the ACA markets.

For example, a reduction in enhanced PTC subsidies may considerably impact pass-through funding to States for programs established under Section 1332 waivers. In 2021, when the enhanced PTC subsidies first took effect, HHS and the Department of the Treasury awarded over \$510 million in additional pass-through funding to 14 States in light of the enhanced subsidies through the ARP.²¹⁰ The expiration of the enhanced PTC subsidies would lead to a reduction in pass-through funding, which could require States to either allocate additional State funding to reinsurance programs or decrease the size of those programs.²¹¹ This could potentially leave States with less State funding to pursue innovative State strategies to further improve affordability or lead to higher premiums. A majority of Section 1332 waiver programs are State-based reinsurance programs.²¹² State-based reinsurance programs aim to reduce

²⁰⁹ For example, permanent extension of enhanced PTC subsidies is discussed in the President's 2025 Fiscal Year Budget (see https://www.whitehouse.gov/wp-content/uploads/2024/03/budget_fy2025.pdf) and the extension of enhanced PTC subsidies has also been addressed by the National Association of Insurance Commissioners in a letter to the U.S. Senate Committee on Finance and the U.S. House of Representatives Committee on Ways and Means (see <https://content.naic.org/sites/default/files/enhanced-subsidies-hill-letter-2024-final-july-2024.pdf>).

²¹⁰ CMS. (2021, Sept. 7). *American Rescue Plan Provides States Additional Funding to Lower Health Coverage Costs, Increase Affordability for Americans*. <https://www.cms.gov/newsroom/press-releases/american-rescue-plan-provides-states-additional-funding-lower-health-coverage-costs-increase>.

²¹¹ An extension of the enhanced PTC subsidies' schedule has previously been projected to increase net Federal spending by about \$18.4 billion in 2026. See OMB. (2024, March). *Budget of the U.S. Government Fiscal Year 2025*. Table S–6 (p. 143). https://www.whitehouse.gov/wp-content/uploads/2024/03/budget_fy2025.pdf. To the extent that a State's 1332 waiver reduces premiums or waives PTC, its 2026 pass-through funding would be higher by a portion of this amount.

²¹² Twenty States have been granted State Innovation Waivers under Section 1332 of the ACA. Of these 20 States, 17 have reinsurance programs. The section 1332 website includes approved waivers here: <https://www.cms.gov/marketplace/states/section-1332-state-innovation-waivers>. Reinsurance programs can also be found here: <https://www.cms.gov/files/document/ccio-data-brief-042024-508-final.pdf>.

²⁰⁵ We considered the most recent projections from the Congressional Budget Office and, as we

premiums for enrollees in the States' individual markets,²¹³ as well as reduce uncertainty in the range of premium increases.²¹⁴ A reduction in the amount of Federal pass-through funding for those programs resulting from the loss of enhanced PTC subsidies would likely have the inverse impact of putting upward pressure on premiums, making premiums higher compared to premiums without the enhanced PTC subsidies. This premium increase could result in lower enrollment and create significant uncertainty about the final combined impact of premium and enrollment changes on FFE and SBE–FP user fees, or it could result in a potentially higher user fee in order to maintain a similar level of user fee funding collections.

Furthermore, the expiration of enhanced PTC subsidies would impact funding available for States to operate BHP programs that enable enrollees that would otherwise be PTC-eligible to purchase healthcare coverage. This includes individuals under age 65 with household incomes between 133 percent and 200 percent of the FPL who are not otherwise eligible for Medicaid, CHIP, or other minimum essential coverage, or individuals whose income is equal to or below 133 percent of FPL but are lawfully present non-citizens ineligible for Medicaid, not otherwise eligible for minimum essential coverage. Expiration of enhanced PTC subsidies may affect BHP States' ability to implement, sustain, and expand their BHP programs, thereby impacting enrollment in these plans.

We also know that the enhanced PTC subsidies have resulted in major enrollment gains in the ACA markets over the last few years.²¹⁵ This is because ACA markets currently consist of additional enrollees who may not have selected plans previously during open enrollment, namely individuals newly eligible to receive tax credits.²¹⁶

²¹³ Overall, from PYs 2018 to 2023, States implementing Section 1332 State-based reinsurance programs for the individual market have seen statewide average SLSP premium reductions ranging from 3.75 percent to 41.17 percent, compared to premiums absent the waiver. See <https://www.cms.gov/files/document/ccio-data-brief-042024-508-final.pdf>.

²¹⁴ Premium growth under reinsurance programs is slower and more stable, and therefore more predictable, than before reinsurance program implementation. See <https://www.cms.gov/files/document/1332-evaluation-oregon-2021.pdf>, <https://www.cms.gov/files/document/1332-evaluation-minnesota-2021.pdf>, and <https://www.cms.gov/files/document/1332-evaluation-alaska-2021.pdf>.

²¹⁵ See <https://www.cms.gov/files/document/early-2024-and-full-year-2023-effectuated-enrollment-report.pdf>.

²¹⁶ From 2022 to 2024, Exchange plan selection during open enrollment for individuals with

Increased enrollment due to enhanced PTC subsidies has increased projected enrollment in our FFE and SBE–FP user fee calculations and has contributed to our ability to lower user fee rates over the past few years.

If enhanced PTC subsidies expire, we project that the total enrollment through FFEs and SBE–FPs would decrease at a similar rate as the Congressional Budget Office projections.²¹⁷ In turn, we anticipate that issuers would likely rate for the uncertainty associated with the expected decreased enrollment in the risk pool and increase premiums, potentially resulting in a decline in issuer participation within ACA markets in the long-term.

Lastly, we note that the expiration of enhanced PTC subsidies is not expected to decrease our FFE and SBE–FP budget estimates for operating the FFEs and SBE–FPs for the 2026 benefit year. This is because, while certain cost estimates would be expected to decrease with the expiration of enhanced PTC subsidies, such as printing and mailing of educational materials to enrollees and QHP certification, other costs and labor estimates would be expected to increase, such as the rate of eligibility appeal cases and inquiries to CMS Agent/Broker Marketplace Help Desks and Call Centers.

Despite the very high level of uncertainty discussed above, we maintain our interest in ensuring that we collect user fees at a rate that will allow us to sustain the operations of the FFEs. After considering the range of costs, premiums, and enrollment projections, and considering how enhanced PTC subsidies could have a notable impact on our FFE and SBE–FP user fee rates, we propose a 2026 user fee rate that will ensure adequate funding for FFE operations. The

incomes $\leq 200\%$ of FPL increased by $\sim 77\%$. For individuals with incomes of $>200\%$ of FPL and $\leq 400\%$ of FPL, enrollment increased by $\sim 15\%$. For individuals with incomes above 400% of FPL, enrollment increased by $\sim 36.7\%$. Prior to the IRA and ARP, individuals with incomes above 400% of FPL were ineligible for the premium tax credit. Data sources: 2022 Marketplace Open Enrollment Period Public Use Files (<https://www.cms.gov/data-research/statistics-trends-reports/marketplace-products/2022-marketplace-open-enrollment-period-public-use-files>) and 2024 Marketplace Open Enrollment Period Public Use Files (<https://www.cms.gov/data-research/statistics-trends-reports/marketplace-products/2024-marketplace-open-enrollment-period-public-use-files>).

²¹⁷ According to Congressional Budget Office projections, Exchange enrollment will peak in 2025 and decline significantly by 2027 due to the expiration of enhanced PTC subsidies in 2025. See Congressional Budget Office and Joint Committee on Taxation projections of net Federal subsidies for health insurance (2023 through 2034): <https://www.cbo.gov/system/files/2024-06/51298-2024-06-healthinsurance.pdf>.

proposed 2026 benefit year FFE user fee rate, which is 2.5 percent of total monthly premiums, is greater than the 2025 benefit year fee rate of 1.5 percent of total monthly premiums. Based on our estimates, this proposed user fee rate would allow us to have sufficient funding available to fully fund user-fee-eligible FFE activities. We note that if any events occurring between this proposed rule and the final rule significantly change our estimated costs to operate the FFEs or the Federal platform, or our projections of premiums or enrollment, we may finalize FFE and SBE–FP user fee rates that differ from these proposed rates to reflect those changes.

We seek comment on the proposed 2026 benefit year FFE user fee rate and the alternative proposed 2026 benefit year FFE user fee rate range (with this range to be set at a single rate in the final rule) if the current or a higher level of enhanced PTC subsidies are extended through the 2026 benefit year by March 31, 2025, including whether March 31, 2025 provides issuers sufficient time to request rates and for States to review and approve rate requests.

b. SBE–FP User Fee Rates for the 2026 Benefit Year

In § 156.50(c)(2), we specify that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an SBE–FP. SBE–FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions and enhance efficiency and coordination between State and Federal programs. The benefits provided to issuers in SBE–FPs by the Federal government include use of the FFE information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs, as defined at section 1413(e) of the ACA, and QHP enrollment functions under 45 CFR part 155, subpart E. The user fee rate for SBE–FPs is calculated based on the proportion of total FFE costs associated with Federal activities that provide SBE–FP issuers with special benefits, including costs that are associated with the FFE information technology infrastructure, the consumer call center

infrastructure, and eligibility and enrollment services.

To calculate the proposed SBE–FP rates for the 2026 benefit year, we used the same assumptions related to contract costs, enrollment, and premiums as we used for the proposed FFE user fee rates. As we explained previously in this section, the user fee rate for SBE–FPs is calculated based on the proportion of the total FFE costs associated with Federal activities that provide SBE–FP issuers with special benefits, which we continue to estimate to be approximately 80 percent of total FFE costs. These FFE costs associated with Federal activities that provide SBE–FP issuers with special benefits include the costs associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services.

Based on this methodology, the proposed 2026 benefit year SBE–FP user fee rate of 2.0 percent of total monthly premiums is greater than the user fee rate of 1.2 percent of total monthly premiums that we established for the 2025 benefit year. The proposed user fee rate for SBE–FP issuers for the 2026 benefit year also includes assumptions about States transitioning from either the FFE model to an SBE–FP, or from an SBE–FP to a State Exchange for the 2026 benefit year, which impacts the SBE–FP enrollment projections.

As discussed in detail above, we believe that the 2026 benefit year is uniquely different due to the potential significant changes to our projections if enhanced PTC subsidies expire at the end of the 2025 benefit year as currently expected. Despite this uncertainty, we maintain our interest in ensuring that we collect user fees at a rate that will allow us to sustain the Federal platform operations for the SBE–FPs. For these reasons, we also propose an alternative SBE–FP user fee range between 1.4 percent and 1.8 percent of total monthly premiums if current or a higher level of enhanced PTC subsidies are extended through the 2026 benefit year by March 31, 2025, to be set at a single rate in the final rule.

We seek comment on the proposed 2026 benefit year SBE–FP user fee rate and the alternative proposed 2026 benefit year SBE–FP user fee rate range (with this range to be set at a single rate in the final rule) if the enhanced PTC subsidies are extended through the 2026 benefit year by March 31, 2025.

3. Silver Loading (\$ 156.80)

Section 1402 of the ACA requires issuers to provide CSRs to help make health care more affordable for eligible

low- and moderate-income consumers who enroll in silver level QHPs offered through the individual market Exchanges, as well as eligible American Indian (AI)/Alaska Native (AN) consumers who enroll in QHPs at any metal level. Section 1402 further states that HHS will reimburse issuers for the cost of providing CSRs. Until October 2017, the Federal government relied on the permanent appropriation at 31 U.S.C. 1324 as the source of funds for Federal CSR payments to issuers. However, on October 11, 2017, the Attorney General of the United States provided HHS and the Department of the Treasury with a legal opinion indicating that the permanent appropriation at 31 U.S.C. 1324 cannot be used to fund CSR payments to issuers.²¹⁸ In light of this opinion—and in the absence of any other appropriation that could be used to fund CSR payments—HHS directed CMS to discontinue CSR payments to issuers until Congress provides an appropriation.

In response to the termination of CSR payments to issuers, State DOIs generally permitted or instructed their issuers to increase premiums only, or primarily, on silver-level QHPs, to compensate for the cost of offering CSRs, since the vast majority of eligible enrollees receiving CSRs are enrolled in silver plans. This rating practice is sometimes referred to as “silver loading” or “actuarial loading.” Our regulations permit certain plan-level adjustments to the index rate on which premiums are based that are actuarially justified pursuant to the single risk pool requirements at \$ 156.80, and many States, which are the traditional regulators of insurance and rating practices, have provided issuers with pricing guidance specific to unpaid CSRs. For enrollees in silver plans who receive PTCs, the increase in PTCs corresponding to the higher premium rates generally fully offsets the higher premiums that they would otherwise experience because of silver loading.

In the January 24, 2019 **Federal Register** (84 FR 283), we sought comments on whether and how we might address the practice of silver loading through rulemaking, in the absence of Congressional action. All commenters recognized silver loading as an appropriate way to maintain consumer affordability and participation. In keeping with States’ longstanding role as regulators of

insurance premium setting, the majority of commenters urged us to continue to allow States to determine how to implement CSR loading. Some commenters expressed opposition to the practice of “broad loading,” in which issuers increase premiums on all plans (on- and off-Exchange) to mitigate the lack of CSR reimbursement. Those commenters stated that increasing premiums for all plans would force all unsubsidized consumers to pay higher premiums and would decrease APTC amounts. Commenters noted the reduction in financial assistance and large premium swings from year to year would cause consumer confusion and instability in the Exchanges, and such market disruption may lead to issuers leaving the Exchanges.

Since the cessation of CSR payments in 2017, States and issuers have asked us to clarify how the single risk pool rules at \$ 156.80 apply to actuarial loading. In guidance published in 2018, we stated that “[a] plan-level variation for the actuarial value and cost-sharing design of a plan is permitted under \$ 156.80(d)(2)(i). A health insurance issuer that offers a QHP may vary premium rates for the QHP based on the impact of the loss of anticipated Federal funding for CSR payments.”²¹⁹ In light of the continued absence of Congressional action to fund CSRs and given States’ longstanding role as the primary regulators of insurance, we have consistently stated that the statute permits States’ rating practices for silver loading or broad-loading, as long as the resulting rate adjustments are reasonable and actuarially justifiable pursuant to \$ 156.80.

Since we continue to receive questions about permissible actuarial loading practices, we affirm that silver-loading and broad-loading practices to increase premiums to offset amounts of unpaid CSRs that are permitted by State regulators are permissible under Federal law to the extent that they are reasonable and actuarially justified. We have long implemented section 1312(c) of the ACA by permitting issuers to vary premium rates for a particular plan from the market-wide adjusted index rate based on a limited set of actuarially justified plan-specific factors, including the actuarial value and cost-sharing design of the plan. For example, reasonable and actuarially justified silver loading practices reflect such a

²¹⁸ Sessions, J. (2017, Oct. 11). *Legal Opinion Re: Payments to Issuers for Cost Sharing Reductions (CSRs)*. Department of Justice’s Office of Attorney General. <https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf>.

²¹⁹ CMS. (2018, Aug. 3). *Center for Consumer Information & Insurance Oversight, Insurance Standards Bulletin Series—Information, Offering of plans that are not QHPs without CSR “loading,”* <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Offering-plans-not-QHPs-without-CSR-loading.pdf>.

permissible variance because they relate to the actuarial value and cost-sharing design of silver-level plans, which are currently required to provide CSRs without reimbursement. We are considering codifying this policy by amending § 156.80(d)(2)(i) to clarify that the plan-specific factors by which issuers adjust the market-wide index rate include adjustments that reflect the costs associated with providing CSRs to the eligible enrollee population, to the extent that such adjustments are reasonable and actuarially justified. We seek comment on whether and how to codify this policy at § 156.80.

4. Publication of the 2026 Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage in Guidance (§ 156.130(e))

As established in part 2 of the 2022 Payment Notice (86 FR 24238), for benefit years in which we are not making changes to the methodology to calculate the premium adjustment percentage, the required contribution percentage, and maximum annual limitations on cost sharing and reduced maximum annual limitation on cost sharing, we will publish these parameters in guidance annually starting with the 2023 benefit year. Therefore, because we are not proposing to change the methodology for calculating these parameters for the 2026 benefit year, these parameters are not included in this rulemaking, and we intend to publish these parameters in guidance no later than December 31, 2024.

5. AV Calculation for Determining Level of Coverage (§ 156.135)

We intend to revise the method for updating the AV Calculator, starting with the 2026 AV Calculator.

Section 2707(a) of the PHS Act and section 1302 of the ACA direct issuers of non-grandfathered individual and small group health insurance coverage, including QHPs, to ensure that plans meet a level of coverage, or metal tier, specified in section 1302(d)(1) of the ACA. Each level of coverage corresponds to an AV calculated based on the cost-sharing features of the plan. On February 25, 2013, HHS published the EHB Rule (78 FR 12834), implementing section 1302(d) of the ACA, which requires at subsection (d)(2)(A) that, to determine the level of coverage for a given metal tier, the calculation of AV be based upon the provision of EHB to a standard population. Section 156.135(a), as

finalized in the EHB Rule, provides that an issuer must use the AV Calculator developed and made available by HHS for the given benefit year to calculate the AV of a health plan, subject to the exception in paragraph (b).

In the 2015 Payment Notice (79 FR 13744), we established at § 156.135(g) provisions for updating the AV Calculator in future plan years. We stated in the preamble of the 2015 Payment Notice that we intend to release a draft version of the AV Calculator and AV Calculator Methodology through guidance for public comment each plan year before releasing the final version. In that same rule, we noted that interested parties could submit feedback on changes to the AV Calculator, and that we would consult as needed with the American Academy of Actuaries and the National Association of Insurance Commissioners on changes to the AV Calculator.

In the 2017 Payment Notice (81 FR 12204), we reiterated this approach and amended § 156.135(g) to allow for additional flexibility in our approach and options for updating the AV Calculator each year, which include trend factor updates, algorithms changes, user interface changes, updates to the claims data and demographic distribution being used in the AV Calculator, and an update to the AV Calculator's annual limitation on cost sharing. We also stated that we intend to release the final AV Calculator for a respective plan year no later than the end of the first quarter of the preceding plan year.

Since this time, we have largely fulfilled this intention. However, we have received feedback that HHS should strive to release the final version of the AV Calculator even sooner, in anticipation of State filing deadlines. SBE-FPs have also provided feedback explaining that they could benefit from an earlier release of the final version of the AV Calculator to design standardized plan options that satisfy the AV de minimis ranges. We believe these requests are reasonable and that we can accommodate them in most years when there are no material changes between the draft and final versions of an AV Calculator for a respective plan year.

Therefore, we intend to revise the current method whereby HHS releases a draft version of the AV Calculator for a respective plan year through guidance for public comment and then releases the final version of the AV Calculator for that plan year no later than the end of the first quarter of the preceding plan year after considering any comments received. We intend to only release the

single, final version of the AV Calculator for a respective plan year. Under this approach, we would still solicit public comments on the AV Calculator for a plan year generally, but we would only plan to incorporate this feedback into the development and release of the following plan year's AV Calculator, rather than to specifically inform the potential revision of the final version of the upcoming plan year's AV Calculator. This approach would allow HHS to release the final AV Calculator sooner. We anticipate that issuers would have the final version of the AV Calculator 3 to 6 months sooner than the end of the first quarter of the preceding plan year.

This approach would not sacrifice the quality of the AV Calculator. The stability and functionality of the AV Calculator has improved every year, and we believe there are diminishing returns to receiving public comments on specific versions of it at this time. This is particularly evident given that we receive fewer than 10 comments on average each year on the draft AV Calculator. In addition, since the first AV Calculator was released for PY 2014, we have never made substantive changes in a final version of the AV Calculator for a plan year based on comments received on the draft version for that plan year, though this feedback is valuable to HHS and informs our decisions to update the AV Calculator in subsequent plan years. This decision to not make substantive changes to the final version of the AV Calculator is also partly influenced by the limited timeframe HHS would have to make substantive changes to the final AV Calculator.

Thus, changes from the draft to the final version of the AV Calculator have historically only included non-substantive amendments to correct and clarify language in the AV Calculator Methodology or to add frequently asked questions to the AV Calculator User Guide. Since these changes have historically been so minor, we believe the time delay required to effectuate those changes and release the final AV Calculator by the end of the first quarter of the preceding plan year is less valuable to issuers than releasing the final version sooner. Under this approach, we would leave open the rare possibility that HHS could reissue another final version of the AV Calculator for a plan year if HHS discovers the AV Calculator contains an error that materially impacts the functionality or accuracy of that version of the AV Calculator. Although this has never happened to date, under the current framework of releasing both a

draft and final version of the AV Calculator, if we had discovered a material error in the final version, we also would have reissued a corrected, final version.

Under this approach, we would still seek public comment on the AV Calculator for a plan year generally and would still consult with the American Academy of Actuaries, as well as the National Association of Insurance Commissioners. We would consider this feedback for incorporation into the following year's AV Calculator.

In order to maximize the benefits of this approach, we intend to make this change effective starting with the release of the 2026 AV Calculator. We believe there will be minimal effect in effectuating this change with the 2026 AV Calculator because we intend to base the 2026 AV Calculator substantially on the final 2025 AV Calculator, and do not plan to make any material changes to it.

We seek comment on this approach.

6. Standardized Plan Options (§ 156.201)

HHS proposes to exercise its authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to make updates to its approach to standardized plan options for PY 2026. Specifically, we propose to make minor updates to the plan designs for PY 2026 to ensure these plans continue to have AVs within the permissible *de minimis* range for each metal level. While we generally propose to maintain a high degree of continuity with the approaches to standardized plan options finalized in the 2023, 2024, and 2025 Payment Notices (87 FR 27310 through 27322, 88 FR 25847 through 25855, and 89 FR 26357 through 26362, respectively), we also propose to amend § 156.201 by adding paragraph (c) to provide that an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area must meaningfully differentiate these plans from one another in terms of included benefits, provider networks, and/or formularies.

Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as QHPs. Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA, which includes section 1311, for, among other matters, the offering of QHPs through such Exchanges.

Standardized options were first introduced in the 2017 Payment Notice (81 FR 12289 through 12293). These plan designs were updated in the 2018

Payment Notice (81 FR 94107 through 94112). The 2018 Payment Notice (81 FR 94118) also introduced the authority for HHS to differentially display these plans on *HealthCare.gov*, which allowed consumers the ability to filter plan options to view only standardized options and receive an accompanying message explaining how standardized options differed from non-standardized options. The 2018 Payment Notice also introduced standardized option differential display requirements for approved web-broker and QHP issuer enrollment partners using a direct enrollment pathway to facilitate consumer enrollment through an FFE or SBE-FP—including both the Classic DE and EDE Pathways.

These plans were then discontinued in the 2019 Payment Notice (83 FR 16974 through 16975). However, the discontinuance was challenged in the United States District Court for the District of Maryland. On March 4, 2021, the court decided *City of Columbus, et al. v. Cochran*.²²⁰ The court reviewed nine separate policies HHS had promulgated in the 2019 Payment Notice, vacating four of them. The court specifically vacated the portion of the 2019 Payment Notice that ceased HHS' practice of designating some plans in the FFEs as "standardized options."

As a result, in part 3 of the 2022 Payment Notice (86 FR 24140, 24264), HHS announced its intent to engage in rulemaking under which it would propose to resume standardized plan options in PY 2023. President Biden's Executive Order on Promoting Competition in the American Economy (86 FR 36987) also directed HHS to implement standardized plan options to facilitate the plan selection process for consumers on the Exchanges. We thus reintroduced standardized plan option requirements in the 2023 Payment Notice (87 FR 27310 through 27322) to enhance the consumer experience, increase consumer understanding, simplify the plan selection process, combat discriminatory benefit designs that disproportionately impact disadvantaged populations, and advance health equity.

We made these requirements applicable to FFE and SBE-FP issuers offering QHPs in the individual market. We exempted FFE and SBE-FP issuers offering QHPs in the small group market as well as issuers in State Exchanges from these requirements. We also exempted issuers of QHPs in FFEs and SBE-FPs that were 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,²²¹ from the requirement to offer the standardized plan options specified by HHS in rulemaking.

In the 2023 Payment Notice (87 FR 27312), we finalized standardized plan options at the following metal levels: one bronze plan, one bronze plan that meets the requirement to have an AV up to 5 points above the 60 percent standard, as specified in § 156.140(c) (known as an expanded bronze plan), one standard silver plan, one version of each of the three income-based silver CSR plan variations, one gold plan, and one platinum plan. We did not finalize standardized plan options for the AI/AN CSR plan variations as provided for at § 156.420(b) given that the cost-sharing parameters for these plan variations are already largely specified.

In the 2023 Payment Notice (87 FR 27312), we finalized two sets of standardized plan options to accommodate different States' cost sharing laws. Specifically, the first set of standardized plan options applied to all FFE and SBE-FP issuers, except issuers in Delaware, Louisiana, and Oregon. The second set of standardized plan options applied only to issuers in Delaware and Louisiana to accommodate these two States' specialty prescription drug cost sharing laws.

We designed these standardized plan options to resemble the most popular QHP offerings that millions of consumers were already enrolled in by taking the following steps: selecting the most popular cost-sharing type for each benefit category; selecting enrollee-weighted median values for each of these benefit categories based on PY 2022 cost sharing and enrollment data; modifying these plans to ensure they were able to comply with State cost sharing laws; and decreasing the AVs for these plan designs to be at the floor of each AV *de minimis* range, primarily by increasing deductibles. We also used the following four tiers of prescription drug cost sharing in these standardized plan options: generic drugs, preferred brand drugs, non-preferred brand drugs, and specialty drugs.

We also resumed the differential display of standardized plan options on *HealthCare.gov* pursuant to § 155.205(b)(1), including those standardized plan options required under State action taking place on or before January 1, 2020. In addition, we resumed enforcing 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

²²⁰ 523 F. Supp. 3d 731 (D. Md. 2021).

²²¹ See Or. Admin. R. 836–053–0009.

SBE-FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively.

As such, web-brokers and QHP issuers have been required to differentially display standardized plan options in accordance with the requirements under § 155.205(b)(1) in a manner consistent with how standardized plan options were displayed on *HealthCare.gov*, unless we approve a deviation. Any requests from web-brokers and QHP issuers seeking approval of an alternate differentiation format were reviewed based on whether the same or a similar level of differentiation and clarity would be provided under the requested deviation as was provided on *HealthCare.gov*.

In the 2024 Payment Notice (88 FR 25847 through 25855), we maintained a high degree of continuity with our approach to standardized plan options finalized in the 2023 Payment Notice. However, in contrast to the policy finalized in the 2023 Payment Notice, we finalized for PY 2024 and subsequent plan years to no longer include a standardized plan option for the non-expanded bronze metal level—primarily due to AV constraints and the infeasibility of designing such a plan. As such, we finalized standardized plan options for the following metal levels: one bronze plan that meets the requirement to have an AV up to 5 points above the 60 percent standard, as specified in § 156.140(c) (known as an expanded bronze plan), one standard silver plan, one version of each of the three income-based silver CSR plan variations, one gold plan, and one platinum plan.

We also removed the regulation text language stating that standardized plan options for the AI/AN CSR plan variations as provided for at § 156.420(b) were not required, to clarify that while issuers must, under § 156.420(b), continue to offer such plan variations based on standardized plan options, those plan variations would themselves not be standardized plan options based on designs specified in rulemaking.²²² We again finalized two sets of standardized plan options applying to issuers in the same sets of States as in the 2023 Payment Notice.

In the 2025 Payment Notice (89 FR 26357 through 26362), we once more maintained a high degree of continuity with the approach to standardized plan options finalized in the 2024 Payment

Notice. In particular, in accordance with § 156.201(b), we finalized standardized plan options for the same metal levels as in the 2024 Payment Notice. We again did not finalize standardized plan options for the AI/AN CSR plan variations as provided for at § 156.420(b) but continued requiring issuers to offer these plan variations for all standardized plan options offered. We once more finalized two sets of standardized plan options with the same sets of designs applying to issuers in the same sets of States as in the 2023 and 2024 Payment Notices.

We refer readers to the preambles to the 2023, 2024, and 2025 Payment Notices discussing § 156.201 (87 FR 27310 through 27322, 88 FR 25847 through 25855, and 89 FR 26357 through 26362, respectively) for more detailed discussions regarding our approaches to standardized plan options in previous plan years.

For PY 2026, we propose to continue following the approach finalized in the 2024 Payment Notice concerning standardized plan option metal levels, and to otherwise maintain a high degree of continuity with our approach to standardized plan options finalized in the 2023, 2024, and 2025 Payment Notices. We once more propose to make minor updates to the plan designs for PY 2026 to ensure these plans continue to have AVs within the permissible *de minimis* range for each metal level. Our proposed updates to plan designs for PY 2026 are detailed in tables 11 and 12, later in this section.

We propose to maintain this high degree of continuity for several reasons. Primarily, we believe maintaining a high degree of continuity will reduce the risk of disruption for all involved interested parties, including issuers, agents, brokers, States, and enrollees. We continue to believe that making major departures from the standardized plan option designs finalized in the 2023, 2024, and 2025 Payment Notices could result in significant changes that may create undue burden for interested parties.

For example, we continue to believe that if the standardized plan options that we create vary significantly from year to year, those enrolled in these plans could experience unexpected financial harm if the cost sharing for services they rely upon differs substantially from the previous year. Ultimately, we continue to believe that consistency in standardized plan options is important to allow issuers and enrollees to become accustomed to these plan designs. As such, the proposed standardized plan options include only modifications to the

deductibles and maximum out-of-pocket limits (MOOPs) for several metal levels, but do not otherwise include modifications to the cost sharing structures.

Although we propose to continue to maintain a high degree of continuity with our approach to standardized plan options in previous years, we propose to amend § 156.201 to add paragraph (c) to require an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area to meaningfully differentiate these plans from one another in terms of included benefits, provider networks, and/or formularies.

This proposal is based in part on our experience with the meaningful difference standard, which was previously codified at § 156.298. The meaningful difference standard was introduced in the 2015 Payment Notice (79 FR 13813 through 13814), revised in the 2017 Payment Notice (81 FR 12312 and 12331), and subsequently discontinued and removed from the regulation in the 2019 Payment Notice (83 FR 17027). The meaningful difference standard was originally intended to enhance the consumer experience on *HealthCare.gov* by preventing duplicative plan offerings and limiting plan proliferation.

Under the original meaningful difference standard introduced in the 2015 Payment Notice (79 FR 13813 through 13814), a plan within a service area and metal tier would be considered meaningfully different from other plans if a reasonable consumer (the typical consumer buying health insurance coverage) would be able to identify at least one material difference among six key characteristics between the plan and other plans to be offered by the same issuer: (1) cost sharing; (2) provider networks; (3) covered benefits (including prescription drugs); (4) plan type (for example, HMO or PPO); (5) health savings account eligibility; and (6) self-only, non-self-only, or child-only plan offerings. Under the original standard, if HHS determined that the plan offerings at a particular metal level within a county were limited, plans submitted for certification at that metal level within that county were not subject to the meaningful difference requirement.

Under the meaningful difference standard revised in the 2017 Payment Notice (81 FR 12312 and 12331), a plan was considered to be “meaningfully different” from other plans in the same service area and metal level if the plan had at least one of the following characteristics: a difference in network ID; a difference in formulary ID; a

²²² See QHP Certification Standardized Plan Options FAQs, <https://www.qhpcertification.cms.gov/s/Standardized%20Plan%20Options%20FAQs>.

difference in MOOP type (specifically, an integrated medical and drug MOOP versus a separated medical and drug MOOP); a difference in deductible type (specifically, an integrated medical and drug deductible versus a separated medical and drug deductible); a difference in the number of in-network tiers; a \$500 or more difference in MOOP; a \$250 or more difference in deductible; or a difference in benefit coverage. The decision to discontinue the meaningful difference standard in the 2019 Payment Notice was made primarily due to the decreased number of plan offerings on the Exchanges.

We propose a meaningful difference standard for PY 2026 and subsequent plan years at § 156.201(c) because several issuers in recent years have offered indistinguishable standardized plan options, and we believe issuers may continue to do so in future plan years partly because the number of non-standardized plan options that issuers can offer is limited in accordance with § 156.202(b). We do not believe it benefits consumers for issuers to offer identical standardized plan options, or standardized plan options that do not differ in meaningful ways, within the same product network type, metal level, and service area. In addition, permitting issuers to offer identical standardized plan options or standardized plan options that do not differ in meaningful ways runs counter to our goals of enhancing the consumer experience, increasing consumer understanding, and simplifying the plan selection process. Allowing issuers to offer duplicative standardized plan options could cause significant consumer

confusion and unnecessary plan proliferation if the trend continues unabated.

As such, under this proposal, although issuers would continue to be permitted to offer multiple standardized plan options within the same product network type, metal level, and service area, these standardized plan options would be required to have meaningfully different benefit coverage, provider networks, and/or formularies. For the purposes of this proposed standard, for PY 2026 and subsequent plan years, we would consider a standardized plan option with a different product, provider network, and/or formulary ID to be meaningfully different, similar to the version of the standard from the 2017 Payment Notice.

In particular, in that rule, we explained that a plan within a service area and metal tier would be considered meaningfully different from other plans if a reasonable consumer (the typical consumer buying health insurance coverage) would be able to identify at least one material differences among several key characteristics between the plan and other plans to be offered by the same issuer. Provider networks and covered benefits (including prescription drugs) were included among the list of key characteristics that would result in a material difference between plans and a plan therefore being considered meaningfully different.

If an issuer submitted two standardized plan options within the same product network type, metal level, and service area both with the same products, provider networks, and formulary IDs, we would not certify

both of these plans. For example, we anticipate that we would seek feedback from the issuer regarding which plan to certify, assuming the issuer meets all other certification requirements. We also note that for the purposes of this proposed standard, we would not consider differences in plan variant marketing names, the availability of different language access features, or the administration of the plan by different vendors in determining whether two or more standardized plan options are meaningfully different.

If this policy is finalized as proposed, we would monitor whether issuers are seeking certification of plans that technically meet this standard but are nearly identical. If we determined that issuers were attempting to circumvent this standard in this manner, we would consider proposing in future rulemaking a version of this meaningful difference standard that would require greater variation among plans beyond product, provider network, and/or formulary IDs. We note that we are not proposing such a standard for PY 2026 and subsequent plan years at this time because, assuming issuers do not attempt to circumvent this standard as explained above, we believe that that this proposed policy would likely be sufficient to ensure that issuers' standardized plan offerings support our goals of enhancing the consumer experience, increasing consumer understanding, and simplifying the plan selection process.

We seek comment on our proposed approach to standardized plan options for PY 2026, including amending § 156.201 to add paragraph (c).

TABLE 11: 2026 Proposed Standardized Plan Options Set One (For All FFE and SBE-FP Issuers, Excluding Issuers in Delaware, Louisiana, and Oregon)

	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	64.42%	70.01%	73.07%	87.04%	94.11%	78.04%	88.03%
Deductible	\$7,500	\$6,000	\$3,000	\$700	\$0	\$2,000	\$0
Annual Limitation on Cost Sharing	\$9,200	\$8,900	\$7,400	\$3,300	\$2,200	\$8,200	\$5,200
Emergency Room Services	60%	40%	40%	30%	25%*	25%	\$100*
Inpatient Hospital Services (Including Mental Health & Substance Use Disorder)	60%	40%	40%	30%	25%*	25%	\$350*
Primary Care Visit	\$60*	\$40*	\$40*	\$20*	\$0*	\$30*	\$10*
Urgent Care	\$90*	\$60*	\$60*	\$30*	\$5*	\$45*	\$15*
Specialist Visit	\$120*	\$80*	\$80*	\$40*	\$10*	\$60*	\$20*
Mental Health & Substance Use Disorder Outpatient Office Visit	\$60*	\$40*	\$40*	\$20*	\$0*	\$30*	\$10*
Imaging (CT/PET Scans, MRIs)	60%	40%	40%	30%	25%*	25%	\$100*
Speech Therapy	\$60*	\$40*	\$40*	\$20*	\$0*	\$30*	\$10*
Occupational, Physical Therapy	\$60*	\$40*	\$40*	\$20*	\$0*	\$30*	\$10*
Laboratory Services	60%	40%	40%	30%	25%*	25%	\$30*
X-rays/Diagnostic Imaging	60%	40%	40%	30%	25%*	25%	\$30*
Skilled Nursing Facility	60%	40%	40%	30%	25%*	25%	\$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	60%	40%	40%	30%	25%*	25%	\$150*
Outpatient Surgery Physician & Services	60%	40%	40%	30%	25%*	25%	\$150*
Generic Drugs	\$25*	\$20*	\$20*	\$10*	\$0*	\$15*	\$5*
Preferred Brand Drugs	\$50	\$40*	\$40*	\$20*	\$15*	\$30*	\$10*
Non-Preferred Brand Drugs	\$100	\$80	\$80	\$60	\$50*	\$60*	\$50*
Specialty Drugs	\$500	\$350	\$350	\$250	\$150*	\$250*	\$150*

*Benefit category not subject to the deductible.

TABLE 12: 2026 Proposed Standardized Plan Options Set Two (For Issuers in Delaware and Louisiana)

	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	64.42%	70.01%	73.09%	87.07%	94.09%	78.02%	88.01%
Deductible	\$7,500	\$6,000	\$3,000	\$700	\$0	\$2,000	\$0
Annual Limitation on Cost Sharing	\$9,200	\$8,900	\$7,400	\$3,300	\$2,400	\$8,300	\$5,300
Emergency Room Services	60%	40%	40%	30%	25%*	25%	\$100*
Inpatient Hospital Services (Including Mental Health & Substance Use Disorder)	60%	40%	40%	30%	25%*	25%	\$350*
Primary Care Visit	\$60*	\$40*	\$40*	\$20*	\$0*	\$30*	\$10*
Urgent Care	\$90*	\$60*	\$60*	\$30*	\$5*	\$45*	\$15*
Specialist Visit	\$120*	\$80*	\$80*	\$40*	\$10*	\$60*	\$20*
Mental Health & Substance Use Disorder Outpatient Office Visit	\$60*	\$40*	\$40*	\$20*	\$0*	\$30*	\$10*
Imaging (CT/PET Scans, MRIs)	60%	40%	40%	30%	25%*	25%	\$100*
Speech Therapy	\$60*	\$40*	\$40*	\$20*	\$0*	\$30*	\$10*
Occupational, Physical Therapy	\$60*	\$40*	\$40*	\$20*	\$0*	\$30*	\$10*
Laboratory Services	60%	40%	40%	30%	25%*	25%	\$30*
X-rays/Diagnostic Imaging	60%	40%	40%	30%	25%*	25%	\$30*
Skilled Nursing Facility	60%	40%	40%	30%	25%*	25%	\$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	60%	40%	40%	30%	25%*	25%	\$150*
Outpatient Surgery Physician & Services	60%	40%	40%	30%	25%*	25%	\$150*
Generic Drugs	\$25*	\$20*	\$20*	\$10*	\$0*	\$15*	\$5*
Preferred Brand Drugs	\$50	\$40*	\$40*	\$20*	\$5*	\$30*	\$10*
Non-Preferred Brand Drugs	\$100	\$80	\$80	\$60	\$10*	\$60*	\$50*
Specialty Drugs	\$150	\$125	\$125	\$100	\$20*	\$100*	\$75*

*Benefit category not subject to the deductible.

7. Non-Standardized Plan Option Limits (§ 156.202)

We propose to exercise our authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to amend § 156.202(b) and (d) to properly reflect the flexibility that issuers have operationally been permitted since the introduction of non-standardized plan option limits to vary the inclusion of distinct adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage categories under the non-standardized plan option limit in accordance with § 156.202(c)(1) through (3).

Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as QHPs. Section 1321(a)(1)(B) of the ACA directs

the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA, which includes section 1311, for, among other things, the offering of QHPs through such Exchanges.

In the 2024 Payment Notice (88 FR 25855 through 25865), we finalized requirements under § 156.202(a) and (b) limiting the number of non-standardized plan options that issuers of QHPs can offer through Exchanges on the Federal platform (including SBE-FPs) to four non-standardized plan options per product network type (as described in the definition of “product” at § 144.103), metal level (excluding catastrophic plans), inclusion of dental and/or vision benefit coverage, and

service area for PY 2024, and two for PY 2025 and subsequent years.

In the 2025 Payment Notice (89 FR 26362 through 26375), we finalized an exceptions process under § 156.202(d) and (e) permitting FFE and SBE-FP issuers to offer more than two non-standardized plan options per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area for PY 2025 and subsequent plan years, if issuers demonstrate that these additional non-standardized plans offered beyond the limit at § 156.202(b) have specific design features that would substantially benefit consumers with chronic and high-cost conditions and meet certain other requirements.

In the 2025 Payment Notice (88 FR 26365 through 26366), we also clarified that the example included in the 2024 Payment Notice that illustrated issuers' flexibility to vary the inclusion of dental and/or vision benefit coverage in accordance with § 156.202(c) under the non-standardized plan option limits at § 156.202(a) and (b) failed to properly distinguish between the adult and pediatric dental benefit coverage categories.

In particular, in the 2024 Payment Notice (88 FR 25858), we stated that for PY 2025, for example, an issuer would be permitted to offer two non-standardized gold HMOs with no additional dental or vision benefit coverage, two non-standardized gold HMOs with additional dental benefit coverage, two non-standardized gold HMOs with additional vision benefit coverage, and two non-standardized gold HMOs with additional dental and

vision benefit coverage, as well as two non-standardized gold PPOs with no additional dental or vision benefit coverage, two non-standardized gold PPOs with additional dental benefit coverage, two non-standardized gold PPOs with additional vision benefit coverage, and two non-standardized gold PPOs with additional dental and vision benefit coverage, in the same service area.

However, in the 2025 Payment Notice, we clarified that in PY 2024, issuers had the ability to vary the inclusion of dental and/or vision benefit coverage (including varying the inclusion of the distinct adult and pediatric dental benefit coverage categories), such that issuers could offer plans in the manner reflected in table 13, below, instead of in the more limited manner reflected in the incomplete example in the 2024 Payment Notice.

In the 2025 Payment Notice, we affirmed that issuers continued to retain

this flexibility for PY 2025 and subsequent years. We thus explained that under the non-standardized plan option limit of two for PY 2025 and subsequent years, if an issuer desired to offer the theoretical maximum number of non-standardized plans, and if that issuer varied the inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage in these plans in accordance with the flexibility provided for at § 156.202(c)(1) through (3), that issuer could offer a theoretical maximum of 16 plans in a given product network type, metal level, and service area in the manner demonstrated in table 13. Furthermore, we explained that if an issuer offered QHPs with two product network types (for example, HMO and PPO), that issuer could offer a theoretical maximum of 32 plans in a given metal level and service area in the manner demonstrated in table 13.

TABLE 13: Issuer Flexibility Under the Non-Standardized Plan Option Limit of Two for PY 2025 and Subsequent Years

Plan	Network Type	Cost Sharing Structure	Adult Dental	Pediatric Dental	Adult Vision
1	HMO	A			
2	HMO	A	Covered		
3	HMO	A		Covered	
4	HMO	A			Covered
5	HMO	A		Covered	Covered
6	HMO	A	Covered		Covered
7	HMO	A	Covered	Covered	
8	HMO	A	Covered	Covered	Covered
9	HMO	B			
10	HMO	B	Covered		
11	HMO	B		Covered	
12	HMO	B			Covered
13	HMO	B		Covered	Covered
14	HMO	B	Covered		Covered
15	HMO	B	Covered	Covered	
16	HMO	B	Covered	Covered	Covered
17	PPO	C			
18	PPO	C	Covered		
19	PPO	C		Covered	
20	PPO	C			Covered
21	PPO	C		Covered	Covered
22	PPO	C	Covered		Covered
23	PPO	C	Covered	Covered	
24	PPO	C	Covered	Covered	Covered
25	PPO	D			
26	PPO	D	Covered		
27	PPO	D		Covered	
28	PPO	D			Covered
29	PPO	D		Covered	Covered
30	PPO	D	Covered		Covered
31	PPO	D	Covered	Covered	
32	PPO	D	Covered	Covered	Covered

As such, we propose to amend the regulation text at § 156.202(b) and (d) to properly reflect the flexibility that issuers have been operationally permitted since we introduced non-standardized plan option limits to vary the inclusion of the distinct adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage under the non-standardized plan option limit at § 156.202(b) in accordance with § 156.202(c)(1) through (3) for PY 2025 and subsequent plan years.

In particular, we propose to amend § 156.202(b) to properly distinguish between adult dental benefit coverage at § 156.202(c)(1) and pediatric dental benefit coverage at § 156.202(c)(2), such that an issuer offering QHPs in an FFE or SBE-FP, for PY 2025 and subsequent

plan years, is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of “product” at § 144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), in any service area.

Consistent with our proposed amendment of § 156.202(b), we propose a conforming amendment to § 156.202(d) to provide that, for PY 2025 and subsequent plan years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental

benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), and service area if it demonstrates that these additional plans’ cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in the issuer’s other non-standardized plan option offerings in the same product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage, and service area.

We propose these modifications to align the regulation text of § 156.202(b) and (d) with the existing flexibility that issuers have been operationally permitted since the non-standardized plan option limit was introduced in the 2024 Payment Notice.²²³

We seek comment on these proposed modifications.

8. Essential Community Provider Reviews for States Performing Plan Management (§ 156.235)

Under § 156.235, we propose to conduct Essential Community Provider (ECP) certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions effective beginning in PY 2026.²²⁴

Section 1311(c)(1)(C) of the ACA directs HHS to establish by regulation certification criteria for QHPs, including criteria that require QHPs to include within health insurance plan networks those ECPs, where available, that serve predominately low-income, medically underserved individuals. Federal ECP standards were first detailed in the Exchange Establishment Rule (77 FR 18310) and codified at § 156.235. ECP certification reviews under § 156.235 ensure medical QHP and stand-alone dental plan (SADP) issuers include in their provider networks a sufficient number and geographic distribution of ECPs, where available.

HHS has relied on State ECP certification reviews for the certification of QHPs in FFEs in States that perform plan management functions since PY 2015 due to system limitations in the Systems for Electronic Rates & Forms Filing (SERFF),²²⁵ which does not have unique network and service area IDs reliably associated with issuers' ECP data. From PY 2015 to PY 2024, prior to HHS' implementation of the user interface logic for ECPs in the Health Insurance Oversight System (HIOS) Marketplace Plan Management System (MPMS),²²⁶ HHS received ECP data via the ECP/Network Adequacy (NA)

Template²²⁷ and SERFF. The ECP/NA Template was an Excel template created by HHS to provide to FFE issuers for collection and submission of both ECP and NA data. While issuers in FFE States would submit the ECP/NA Template with ECP data to HHS directly, issuers in FFEs in States performing plan management functions would not use the ECP/NA Template, but rather submit the ECP data to SERFF.²²⁸ Since there was no reliable mechanism for HHS to convert ECP data received from SERFF back into the ECP/NA Template for review and analysis of the data, HHS could not conduct ECP reviews for issuers in FFEs in States performing plan management functions and therefore relied on States to perform those ECP certification reviews. In the SERFF data, each plan has its own ECP template with its own set of ECPs and networks. The SERFF data does not allow HHS to conduct accurate ECP evaluations of each issuer's networks because multiple networks can share the same sequence number within the SERFF data, making them indistinguishable from each other in the issuer's SERFF binder. Initially, HHS designed a workaround to merge the SERFF issuer templates across each plan and remove duplicate entries to allow HHS to conduct the review at the plan level; but this workaround still did not allow for independent evaluation of each issuer's provider networks that share the same sequence number.

As a result of HHS' system design enhancements via MPMS, HHS is now able to collect ECP data directly from issuers in States performing plan management functions, enabling HHS to conduct ECP evaluations of each issuer's network. Starting with certification reviews for PY 2025, issuers seeking certification of plans as QHPs in FFEs, including in States performing plan management functions, can now enter their ECP data in the HIOS MPMS using the ECP user interface. Because ECP data can now be collected directly in MPMS from issuers applying for certification of plans as QHPs in FFEs in States performing plan management functions, HHS will now be able to independently review the ECP data for such issuers.

Now, the MPMS ECP user interface also allows issuers in FFEs, including in

States performing plan management functions, to validate data before submission to their States, improving data submission to the State as well as providing HHS with each issuer's provider network. Therefore, HHS will now be able to assess validated ECP data, improving the accuracy and efficiency of the QHP certification process.

It was always HHS' intent to implement operational capabilities that would allow for more efficient and accurate ECP reviews. As a result, we propose to harness the flexibilities afforded by MPMS to conduct Federal ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States that perform plan management functions beginning with certification reviews for PY 2026. This proposal would allow HHS to review, evaluate, analyze, and compare provider networks across various FFE States. HHS would also consider challenges FFE issuers face across various provider networks and ECP categories, such as provider shortages or facility closures. As proposed, issuers applying for certification of plans as QHPs in FFEs, including in States performing plan management functions, would be evaluated against the same requirements and standards. FFE issuers in States with limited plan management staff or resources would be given the same ECP support, guidance, and monitoring of ECP deficiencies as other FFE issuers.

This proposal would provide more consistent oversight of ECP data across all FFEs. Federal ECP reviews would help ensure all medical QHP and SADP issuers applying for certification of plans as QHPs in FFEs, including in States performing plan management functions, include sufficient provider networks. This proposal would allow HHS to strengthen ECP data integrity in the FFEs by validating all ECP data before they are submitted and displayed on the FFEs, thereby supporting consumer access to vitally important medical and dental services and health equity for low-income and medically underserved consumers.

We seek comment on this proposal.

9. Quality Improvement Strategy (§ 156.1130)

We propose to share aggregated, summary-level Quality Improvement Strategy (QIS) information publicly on an annual basis beginning on January 1, 2026, with information QHP issuers submit during the PY 2025 QHP Application Period. We do not propose any revisions to the regulation text to codify this proposal.

²²³ CMS. (2024, April 10). 2025 Final Letter to Issuers in the Federally-facilitated Exchanges. <https://www.cms.gov/files/document/2025-letter-issuers.pdf>.

²²⁴ Twelve FFEs operate in States performing plan management functions: Delaware, Hawaii, Iowa, Kansas, Michigan, Montana, Nebraska, New Hampshire, Ohio, South Dakota, Utah, and West Virginia.

²²⁵ Systems for Electronic Rates & Forms Filing (SERFF) is a portal utilized by States for form submittal, document management, and review.

²²⁶ HIOS MPMS is a web application where users can validate plan data as well as submit their QHPs and SADPs to CMS for annual review and certification.

²²⁷ OMB Control Number 0938-1415: Essential Community Provider-Network Adequacy (ECP/NA) Data Collection to Support QHP Certification (CMS-10803).

²²⁸ For PY 2025 there were 13 FFEs that operate in States performing plan management functions: Delaware, Hawaii, Illinois, Iowa, Kansas, Michigan, Montana, Nebraska, New Hampshire, Ohio, South Dakota, Utah, and West Virginia.

Section 1311(c)(1)(E) of the ACA specifies that to be certified as a QHP for participation on an Exchange, each health plan must implement a QIS 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 for improving health outcomes of plan enrollees, and the implementation of activities to prevent hospital readmissions, improve patient safety and reduce medical errors, promote wellness and health, and reduce health and health care disparities. Section 1311(g)(2) of the ACA requires the Secretary to develop guidelines associated with the QIS in consultation with health care quality experts and interested parties, including periodic reporting to the applicable Exchange of the activities that the plan has conducted to implement the QIS, as described in section 1311(g)(3) of the ACA. In the 2016 Payment Notice (80 FR 10844 through 10845), we issued regulations at § 156.1130(a) and (c) to direct eligible QHP issuers to implement and report on their QIS for each QHP offered in an Exchange, and to submit data annually to evaluate compliance with the standards for a QIS in a manner and timeline specified by the Exchange, respectively.²²⁹ In addition, in the Exchange Establishment Rule (77 FR 18324 and 18415), we finalized regulations at § 155.200(d) that direct Exchanges to evaluate each QIS, and § 156.200(b)(5) that direct QHP issuers to implement and report on a QIS consistent with ACA section 1311(g) standards as QHP certification criteria for participation in an Exchange.

The CMS National Quality Strategy,²³⁰ launched in 2022, builds on previous efforts to improve quality across the health care system. We continue to use a variety of levers across the agency, including but not limited to quality measurement, public reporting and quality improvement programs, to improve health care quality for all. One of the four priority areas of the CMS National Quality Strategy is to promote alignment and coordination across programs and care settings and to improve quality and health outcomes across the care journey.²³¹ By developing aligned approaches across quality programs, we can improve coordination and comparisons across

programs and across the continuum of care and build the evidence base for quality interventions to support identifying disparities in care. Across Medicare, Medicaid and Exchange quality programs and initiatives, we promote sharing health care quality information with consumers, providers, researchers and others using different methods such as the Care Compare website,²³² and program experience reports. Specifically, for the Quality Rating System (QRS) program, we share a summary of quality ratings for each plan year in an annual Results at a Glance report.²³³ Additionally, we share information pertaining to both the QRS and QHP Enrollee Experience Survey programs with the public annually through the same report.²³⁴ Our proposal to share aggregated, summary-level QIS information publicly is consistent with the goal of these Marketplace Quality Initiatives (MQIs) to share information publicly and is in alignment with agency efforts to drive innovation and advance quality improvement across the Exchanges.

Since 2017, we have been collecting QIS information from QHP issuers on the FFEs. Over the years, we have received feedback from issuers, States, and Technical Expert Panel representatives about the benefits of sharing QIS data more broadly to promote transparency, improve engagement of best practices across QHP issuers, and provide consumers with useful information about quality improvement efforts by QHP issuers on the FFEs. Therefore, recognizing the general interest in this information, and consistent with the general authority set forth in section 1701(a)(8) of the PHS Act,²³⁵ we propose to release annually, in a report format, the following aggregated, summary-level QHP issuer data: (1) value-based payment models used in QHPs offered by the issuer; (2) QIS topic area; (3) QIS market-based incentive types; (4) clinical areas addressed by QIS; (5) QIS activities; and (6) QRS measures used in QIS. We do

not receive QIS data from State Exchanges or SBE-FPs and would not collect QIS data from State Exchanges or SBE-FPs or their respective issuers under this proposal. As such, the report would provide information on QIS programs adopted by issuers offering QHPs in the FFEs.

We believe that this proposal would promote transparency of data and drive innovation and quality improvement across Exchanges. Sharing QIS data publicly would also strengthen alignment across CMS quality reporting and value-based incentive programs, including the MQI programs, and would encourage learning to inform best practices for quality improvement across Exchanges, QHP issuers, researchers, and health care quality communities. Additionally, we believe that this proposal would increase accountability for QHP issuers through transparency of quality improvement goals, encourage State Exchanges to share QIS information from their State Exchange issuers publicly, and support HHS' mission to achieve optimal health and well-being for all individuals.

We acknowledge there may be concerns related to the potential sharing of proprietary and/or confidential information. However, we do not intend to share confidential or proprietary information from a QHP issuer and would only share QIS data that is de-identified and in summary and aggregate form. We would maintain compliance with CMS privacy policies, and to address potential confidentiality concerns, we would carefully redact and omit confidential data when data are released aggregately and in a summary format.

We seek comment on this proposal. In particular, we seek comment on the types of QHP issuer QIS data to release in an annual report, on the proposed approach and timeline for release of a QIS summary report with aggregated QIS data, and other potential mechanisms to present QIS information publicly in a manner that is informative to issuers and consumers.

10. HHS–RADV Materiality Threshold for Rerunning HHS–RADV Results (§ 156.1220(a)(2))

We propose to amend § 156.1220(a) to codify a second, new materiality threshold for HHS–RADV appeals,²³⁶ hereafter referred to as the materiality threshold for rerunning HHS–RADV

²²⁹ Refer to OMB control number 0938–1286.

²³⁰ The CMS National Quality Strategy for Quality Improvement in Health Care available at <http://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy>.

²³¹ Id.

²³² See Care Compare at <https://www.cms.gov/medicare/quality/physician-compare-initiative>.

²³³ See, for example, Health Insurance Exchanges Quality Rating System (QRS) for Plan Year (PY) 2024: Results at a Glance, available at <https://www.cms.gov/files/document/health-insurance-exchanges-qrs-program-plan-year-2024-results-glance.pdf>.

²³⁴ See, for example, Health Insurance Exchanges Quality Rating System (QRS) for Plan Year (PY) 2024: Results at a Glance, available at <https://www.cms.gov/files/document/health-insurance-exchanges-qrs-program-plan-year-2024-results-glance.pdf>.

²³⁵ Section 1701(a)(8) of the PHS Act, codified at 42 U.S.C. 300u(a)(8), provides general authority to the Secretary of HHS to foster exchange of health-related information to consumers and others.

²³⁶ For the purposes of this proposal, “appeals” refers to all three steps of the administrative appeals process as listed in § 156.1220, which includes the request for reconsideration, informal hearing, and review by the Administrator of CMS.

results.²³⁷ This proposal would codify a standard for when HHS would take action to rerun HHS–RADV results and adjust HHS–RADV adjustments to State transfers in response to a successful appeal. We propose to make amendments to § 156.1220 to add a new paragraph (a)(2)(i) to provide that HHS would rerun HHS–RADV results in response to an appeal when the impact to the filing issuer's (that is, the issuer who submitted the appeal) HHS–RADV adjustments to State transfers is greater than or equal to \$10,000, and we propose to apply this second, new materiality threshold beginning with 2023 benefit year HHS–RADV.²³⁸

An issuer has the opportunity to submit a request for reconsideration to contest its HHS–RADV second validation audit results (if applicable) or its error rate calculations in accordance with § 156.1220(a)(1)(vii) and (viii).²³⁹ 240 An issuer can also request an informal hearing before a CMS hearing officer to appeal HHS' reconsideration decision in accordance with § 156.1220(b) and may request review by the CMS Administrator of the CMS hearing officer's discretion as outlined in § 156.1220(c). Currently, § 156.1220(a)(2) specifies that an issuer may file an HHS–RADV request for reconsideration if the amount in dispute is equal to or exceeds 1 percent of the applicable payment or charge from the issuer for the benefit year, or \$10,000, whichever is less. However, the current regulations do not specify when HHS is required to rerun HHS–RADV results in response to an appeal. This allows for the possibility of an appeal being filed

that, if granted, in its totality would result in an impact of \$10,000 or 1 percent of the applicable payment or charge for the issuer for the benefit year, whichever is less. HHS may therefore be put into a position to rerun HHS–RADV results if any portion of that appeal is accepted by HHS, even if that portion has a much smaller impact than the materiality threshold to file the appeal. Based on our experience operating HHS–RADV since the 2017 benefit year, we determined there would be a benefit from codifying a second materiality threshold to address when HHS would be required to rerun HHS–RADV results in response to successful appeals. This second materiality threshold would promote the stability of HHS–RADV and avoid considerable expenditures to rerun HHS–RADV results in situations where the filing issuer only accrues a very minor financial benefit (in this case defined as less than \$10,000), if any, and where there is a non-material impact on State transfers in a State market risk pool. By way of example, assume an issuer submits an appeal of its SVA results or HHS–RADV error rate calculation that contests the determination for 35 HCCs, of which 3 HCCs are validated during the appeal process. In this example, assume that the consequences of those modified results impact other issuers (non-filing issuers) and shift the national benchmarks to determine error rate outliers in HHS–RADV, but the filing issuer receives a benefit of only \$100. In this situation, applying the proposed materiality threshold for rerunning HHS–RADV results, HHS would not spend the significant resources for itself and issuers to rerun HHS–RADV, recalculate HHS–RADV adjustments to State transfers, re-release HHS–RADV results, complete another discrepancy and appeal window for the reissued results, engage in netting and send new invoices to issuers, collect charges and redistribute payments for the reissued HHS–RADV adjustments to State transfers in response to the successful appeal. In contrast, if the impact on the filing issuer was material (that is, greater than or equal to \$10,000), the impact on other issuers (non-filing issuers) would also likely be more significant, and HHS would engage in the significant effort to re-run HHS–RADV results.

We believe the adoption of the proposed additional materiality threshold to codify a standard for when HHS would rerun HHS–RADV results is necessary and appropriate because HHS–RADV is unique in comparison to other ACA financial programs, such as APTC, where the outcome of a

successful appeal only impacts the filing issuer because an issuer's amount of APTC does not impact other issuers.²⁴¹ Instead, an HHS–RADV appeal has the potential to impact all issuers nationwide who participated in the applicable benefit year's HHS–RADV.²⁴² More specifically, because HHS–RADV uses HCC-based group failure rates from all issuers that participate in HHS–RADV for the benefit year being audited, the inclusion or exclusion of even one HCC can result in a change in the national program benchmarks that apply to all issuers nationwide who participated in HHS–RADV in the applicable benefit year. The national program benchmarks are used to create confidence intervals for outlier identification and calculate outlier issuers' error rates. Therefore, changes to the national program benchmarks may result in changes to the outlier status or error rates of all issuers, due not to an error in their own data, but as a result of an HHS decision on another issuer's HHS–RADV appeal. In these situations when there are minor adjustments, this would result in all issuers in States with an error rate outlier receiving small changes to their HHS–RADV adjustments to State transfers as a result of one issuer's successful HHS–RADV appeal.

To further explain the uniqueness of HHS–RADV, we want to compare the existing HHS–RADV appeal materiality threshold at § 156.1220(a)(2) to that of the EDGE data discrepancies in § 153.630(d)(2). Under § 153.630(d)(2), upon receipt of an EDGE data discrepancy, the impact is first analyzed by HHS, and the entirety of an impact must reach the materiality threshold in order for HHS to take further action. However, unlike HHS–RADV appeals that have the potential to impact the national HHS–RADV results, EDGE data discrepancies typically only impact the issuers at the State market risk pool level and therefore, they do not have the potential to trigger the same national level of adjustments that can be

²³⁷ For purposes of this proposal, rerunning HHS–RADV results involves recalculating all national program benchmarks and issuers' error rate results, reissuing issuers' error rate results, conducting discrepancy reporting and appeal windows for the reissued results, applying the reissued error rates to the applicable benefit year's State transfers, and invoicing, collecting, and distributing any additional changes to the HHS–RADV adjustments to State transfers.

²³⁸ The appeal window for 2023 benefit year HHS–RADV is expected to open in July 2025, after the tentative July publication of the Summary Report of 2023 Benefit Year HHS–RADV Adjustments to 2023 Benefit Year Risk Adjustment Transfers. Therefore, we are proposing to adopt and apply the materiality threshold for rerunning HHS–RADV results beginning with 2023 benefit year HHS–RADV. See the *2023 Benefit Year HHS–RADV Activities Timeline*. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.

²³⁹ Issuers are not permitted to file a request for reconsideration or appeal the results of the IVA audit. See 81 FR 94106 and 84 FR 17495.

²⁴⁰ Consistent with § 156.1220(a)(4)(ii), an HHS–RADV request for reconsideration may be requested only if, to the extent the issue could have been previously identified, the issuer notified HHS of the dispute through the applicable process for reporting a discrepancy set forth in § 153.630(d)(2) and (3), it was so identified, and remains unresolved.

²⁴¹ The EDGE data discrepancies that can arise in States where the HHS-operated risk adjustment program applies have a more limited reach and only impact the State market risk pool with the discrepancy.

²⁴² The impact of successful HHS–RADV requests for reconsideration or appeals on HHS–RADV results and HHS–RADV adjustments to risk adjustment State transfers on all participating issuers also differs from that of high-cost risk pool audits, discrepancies, and appeals. Any high-cost risk pool funds HHS recoups as a result of audits of risk adjustment covered plans, actionable discrepancies, or successful appeals are used to reduce high-cost risk pool charges for that national high-cost risk pool in the next applicable benefit year for which high-cost risk pool payments have not already been calculated. See 87 FR 27253.

triggered by successful HHS–RADV appeals. When evaluating HHS–RADV requests for reconsideration, the entirety of the reconsideration request is used to determine materiality, regardless of what portion of that reconsideration request is found to have merit. For example, an issuer can include 25 HCCs in an HHS–RADV request for reconsideration, and upon review, HHS can find that one of them has merit and the other 24 do not. Under the existing materiality threshold at § 156.1220(a)(2), the materiality determination is based on the impact that accepting all 25 HCCs in the request for reconsideration would have on HHS–RADV results, rather than the impact of the one HCC determined to be meritorious.

Because an HHS–RADV appeal can impact national program benchmarks and the HHS–RADV results and HHS–RADV adjustments of issuers nationally, we believe that the adoption of this proposed additional materiality threshold to specify when HHS would rerun HHS–RADV results would help ensure stability of HHS–RADV results for all issuers. In particular, HHS–RADV adjustments to State transfers already occur 2 years after the end of the applicable benefit year. Rerunning HHS–RADV results in response to a successful appeal could occur years later depending on the complexity of the issues raised and whether the matter involves an informal hearing under § 156.1220(b) or a request for CMS Administrator review under § 156.1220(c). After the initial issuance of HHS–RADV adjustments, issuers generally have already closed their books for the applicable benefit year, and we are concerned that rerunning HHS–RADV results as a result of a successful HHS–RADV appeal that would not meet the proposed additional materiality threshold would require issuers to reopen their books years later, increasing burden and creating instability for issuers of risk adjustment covered plans to account for minor adjustments. In these situations, we are of the opinion that the benefit of the minor adjustment would be outweighed by the costs and burdens associated with rerunning HHS–RADV results to account for the additional minor adjustment to State transfers.

We also note that it is burdensome to HHS to rerun HHS–RADV results, especially in situations where there is a small financial impact. Because of the budget-neutral nature of the HHS-operated risk adjustment program, including HHS–RADV, the costs associated with rerunning HHS–RADV are passed onto the issuers in the form of the risk adjustment user fees.

Therefore, we believe that creating an additional materiality threshold for rerunning HHS–RADV results recognizes that an appeal must have a meaningful financial impact to justify the costs and burdens to HHS and issuers of rerunning HHS–RADV results. This would balance the policy goals of ensuring that processing errors, the incorrect application of the relevant methodology, or mathematical errors in HHS–RADV that have a material impact are appropriately addressed, while minimizing burden on issuers and HHS and promoting the stability of State transfers by not rerunning HHS–RADV results when there would be minor adjustments. For all of these reasons, we propose to adopt an additional materiality threshold for HHS–RADV appeals to provide a standard for when HHS would rerun HHS–RADV results. To align with § 153.710(e), we propose to apply this materiality threshold for rerunning HHS–RADV results based on the financial impact on the filer as we believe that issuers submit HHS–RADV appeals with the expectation that their acceptance would meaningfully benefit them financially. Thus, we believe that structuring the threshold based on the financial impact on the filer would ensure that HHS–RADV results are being rerun in situations where the impact of the HHS–RADV appeal is meaningful to the issuer that triggered the process and would have a material impact on other issuers that participate in HHS–RADV in the applicable benefit year.

We also reaffirm under this proposed policy that if the impact of the appeal meets the proposed materiality threshold for rerunning HHS–RADV results (that is, greater than or equal to \$10,000 to the filing issuer's HHS–RADV adjustments for the applicable benefit year), HHS would rerun the HHS–RADV results for that benefit year. However, if the impact of the appeal is less than proposed materiality threshold for rerunning HHS–RADV results (that is, less than \$10,000 to the filing issuer's HHS–RADV adjustment), then HHS would take no further action. That is, HHS would not rerun HHS–RADV results or make any changes to the HHS–RADV adjustments for the filing issuer or other issuers that participated in HHS–RADV for that benefit year if the new proposed materiality threshold is not met.

We solicit comments on the proposed materiality threshold for rerunning HHS–RADV results, including the proposed dollar amount for the materiality threshold and whether that dollar amount should be a higher or lower dollar amount or subject to an

annual inflation adjustment amount, as well as the proposed applicability of this threshold beginning with 2023 benefit year HHS–RADV.

E. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Definitions (§ 158.103)

We propose to amend § 158.103 by adding a definition of “qualifying issuer.” See subsection E.2 below for the discussion of this proposal.

2. Reimbursement for Clinical Services Provided to Enrollees (§§ 158.140, 158.240)

We propose to amend § 158.140(b)(4)(ii) to allow qualifying issuers to not adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes beginning with the 2026 MLR reporting year (MLR reports due in 2027). We also propose to amend § 158.240(c) to add an illustrative example of how qualifying issuers would calculate the amount of rebate owed to each enrollee to accurately reflect how such issuers would incorporate the net risk adjustment transfer amounts into the MLR and rebate calculations differently from other issuers, as well as to make a conforming amendment to clarify that the current illustrative example in paragraph (c)(2) would apply to issuers that are not qualifying issuers.

Section 2718 of the PHS Act and the implementing regulations at 45 CFR part 158 require health insurance issuers offering group or individual health insurance coverage to submit an annual report to the Secretary of HHS concerning their MLR and issue an annual rebate to enrollees if the issuer's MLR is less than the applicable MLR standard established in sections 2718(b)(1)(A)(i) and (ii) of the PHS Act. Under section 2718 of the PHS Act, an issuer's MLR is defined as the ratio of (a) incurred claims and quality improvement activity expenses, to (b) premium revenue after subtracting taxes and licensing and regulatory fees and accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341 1342, and 1343 of the ACA. The statute also defines the total amount of an issuer's annual rebate as an amount equal to the product of the amount by which the applicable MLR standard exceeds the issuer's MLR, multiplied by the issuer's premium revenue after subtracting taxes and licensing and regulatory fees and accounting for payments or receipts for

risk adjustment, risk corridors, and reinsurance under sections 1341 1342, and 1343 of the ACA.

In contrast, section 1342(c) of the ACA provides that allowable costs shall be reduced by any risk adjustment payments in the numerator of the risk corridors calculation.²⁴³ In order to preserve consistency between these two programs, we finalized an approach in the 2014 Payment Notice (78 FR 15504) that accounted for all premium stabilization program²⁴⁴ amounts, other than reinsurance contribution fees, in a way that would not have a net impact on the adjusted earned premium revenue used in the calculation of the MLR denominator as defined in § 158.130. Specifically, in the 2014 Payment Notice, we explained that to account for premium stabilization program amounts as an adjustment to earned premium under § 158.130(b)(5), net risk adjustment program receipts, net risk corridors program receipts, and reinsurance program payments would be added to total premium and then subtracted from adjusted earned premium. Section 158.140(b)(4) also provided that premium stabilization amounts, other than reinsurance contribution fees, must adjust incurred claims in the numerator of the MLR calculation defined in § 158.221, in a manner similar to the adjustment of allowable costs in the risk corridors formula set forth in § 153.500. As stated in the 2014 Payment Notice, we found that this approach adhered to the statutory construct of the MLR formula in section 2718 of the PHS Act, which we believe provides flexibility as to whether to account for the effects of collections or receipts for the premium stabilization programs in determining revenue (the denominator) or costs (the numerator) of the MLR formula, while also aligning with the treatment of risk adjustment transfer amounts and reinsurance payments in the calculation of risk corridors payments and charges under section 1342 of the ACA.

While most commenters on the 2014 Payment Notice proposed rule (77 FR 73187) supported the proposal to treat premium stabilization program amounts as an adjustment to incurred claims in

the numerator of the MLR calculation, some commenters noted that risk adjustment transfer amounts are calculated based on the statewide average premium in a market, and asserted that it would, therefore, be more appropriate to include risk adjustment transfer amounts as a net adjustment to earned premium in § 158.130, which is included in the denominator of the MLR calculation in § 158.221(c). We recognized the validity of both perspectives in the 2014 Payment Notice, noting that either approach could be implemented in accordance with the statutory requirements for the MLR calculation set forth in section 2718 of the PHS Act, and finalized the proposal to treat premium stabilization amounts as an adjustment to incurred claims in the numerator of the MLR calculation to ensure consistency between the MLR and the risk corridors programs.

We recognize that although we generally assume that plans are pricing for average risk, our experience has shown that some issuers with plans with especially high or low claims costs may not necessarily price their offerings commensurate to these costs. While treating risk adjustment transfer amounts as either an adjustment to incurred claims in the numerator of the MLR calculation or an adjustment to premiums in the denominator of the MLR calculation may not significantly impact issuers with claims costs and premiums ratios that approximate the MLR standard and that closely approximate average risk, if an issuer's plan offerings are significantly mispriced or if its earned premiums are influenced by external factors, such as State subsidies, such an issuer could be in a position of owing rebates that are a substantial portion of its premium under the current MLR calculation methodology, despite also incurring very high claims costs and receiving large risk adjustment payments. In rare cases, these high rebate amounts may result in solvency concerns for these types of issuers with very high-risk populations and high claims expenses.

While many complex factors influence an issuer's underwriting position, our internal analysis suggests that issuers with unusual business models characterized by ratios of risk adjustment payments to earned premium that are approximately 50 percent or higher may owe disproportionately large MLR rebates that could impact solvency. In these circumstances, we believe that the way the current MLR methodology functions is misaligned with one of the primary statutory goals of the program, which is

to ensure that consumers receive value for their premium dollars, as issuers with especially high-risk populations spend a significant proportion of their revenue paying medical claims and may nonetheless also owe rebates that make continued operation in their current markets untenable. Consistent with section 2718(c) of the PHS Act, the standardized methodologies for calculating an issuer's MLR "shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans." We believe that modifying the treatment of risk adjustment transfer amounts in the MLR and rebate calculations for these issuers such that these amounts have a net impact on the MLR denominator rather than on MLR numerator would mitigate the solvency and stability concerns for this small subset of issuers that offer different types of plans with unique business models. Specifically, this proposed change would support the viability of issuers that offer different types of plans with unique business models that focus on underserved communities with significant rates of serious health conditions and that may disproportionately rely on risk adjustment payments, as opposed to premiums, for revenue.

HHS has in the past exercised its authority under section 2718(c) of the PHS Act to take into account the special circumstances of different types of plans by providing adjustments to increase the MLR numerator for "mini-med" and "expatriate" plans,²⁴⁵ student health insurance plans,²⁴⁶ as well as for QHPs that incurred Exchange implementation costs²⁴⁷ and certain non-grandfathered plans (that is, "grandmothered" plans).²⁴⁸ This authority has also been exercised to recognize the special circumstances of new plans²⁴⁹ and smaller plans,²⁵⁰ as well as the new and different types of plans that provide "shared savings" to consumers who

²⁴³ Section 1342 of the ACA and the implementing regulations at 45 CFR part 153 established a temporary risk corridors program applicable to QHP issuers in the individual and small group (or merged) markets for the 2014, 2015, and 2016 benefit years.

²⁴⁴ The premium stabilization programs refer to the reinsurance, risk corridors, and risk adjustment programs established by the ACA. See section 1341 of the ACA (transitional reinsurance program), section 1342 of the ACA (risk corridors program), and section 1343 of the ACA (risk adjustment program).

²⁴⁵ See 45 CFR 158.221(b)(3) for "mini-med" plans and 45 CFR 158.221(b)(4) for "expatriate" plans. See also the Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act Interim Final Rule, 75 FR 74864, 74872 (December 1, 2010).

²⁴⁶ See 45 CFR 158.221(b)(5). See also the Student Health Insurance Coverage Final Rule, 77 FR 16453, 16458 through 16459 (March 21, 2012).

²⁴⁷ See 45 CFR 158.221(b)(7). See also the 2015 Market Standards Rule, 79 FR 30240, 30320 (May 27, 2014).

²⁴⁸ See 45 CFR 158.221(b)(6). See also 79 FR 30320 (May 27, 2014).

²⁴⁹ See 45 CFR 158.121. See also 75 FR 74872 through 74873 (Dec. 01, 2010) and the 2018 Payment Notice, 81 FR 94058, 94153 through 94154 (Dec. 22, 2016).

²⁵⁰ See 45 CFR 158.230 and 158.232. See also 75 FR 74880 (Dec. 01, 2010).

choose lower-cost, higher-value providers.²⁵¹

Consistent with this approach, we propose to exercise our authority to account for the special circumstances of the small subset of issuers that offer different types of plans with unique business models that receive risk adjustment payments and that are unable to reduce premiums sufficiently to meet the MLR standard without risking insolvency (hereinafter referred to as “qualifying issuers”). We propose to exercise this authority to narrowly extend flexibility for the manner in which risk adjustment transfer amounts must be reported by these qualifying issuers. Specifically, we propose to amend § 158.103 to add a definition of “qualifying issuer” to mean an issuer whose ratio of net payments related to the risk adjustment program under section 1343 of the ACA to earned premiums prior to accounting for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs (as described in § 158.130(b)(5)) in a relevant State and market is greater than or equal to 50 percent. We also propose to modify § 158.140(b)(4)(ii) to no longer apply net risk adjustment receipts as an adjustment to the incurred claims amount that is used to calculate the MLR numerator defined in § 158.221(b) for such qualifying issuers. We do not propose to make any changes to the definition of premium revenue in § 158.130.

Under this proposal, we would modify the calculation of the MLR denominator and rebates as described in the 2014 Payment Notice such that for qualifying issuers, earned premium would account for net risk adjustment receipts by simply adding these net receipts to total premium, without subsequently subtracting them from adjusted earned premium. The effect of these proposed changes would be to remove these offsetting adjustments (the addition and the subtraction that offset each other) to earned premium in the MLR denominator and rebate calculations, such that these qualifying issuers’ risk adjustment transfer amounts would have a net impact on the MLR denominator and rebate calculations in § 158.221(c) and § 158.240(c), respectively. We also propose to make a conforming amendment to § 158.240(c) to clarify that the existing illustrative example in paragraph (c)(2) would apply to issuers that are not qualifying issuers, and to

add an illustrative example in a new paragraph (c)(3) of how qualifying issuers would determine the amount of rebate owed to each enrollee, to accurately reflect how qualifying issuers would incorporate the net risk adjustment transfer amounts into the MLR and rebate calculations differently from other issuers.

We note that we are not proposing any changes that would alter the current treatment of Federal transitional reinsurance amounts in the MLR formula. Section 2718 of the PHS Act specified that Federal transitional reinsurance amounts under section 1341 of the ACA be accounted for in the denominator of the MLR calculation, while the Federal transitional reinsurance program expired after the 2016 benefit year, audit activities continue²⁵² and could result in changes to the amounts previously provided. In addition, maintaining this treatment is consistent with the NAIC recommendations for the treatment of payments under State reinsurance programs (for example, those provided to issuers through a State-based reinsurance program established under section 1332 waivers), which are accounted for as an adjustment to incurred claims in § 158.140(b)(2)(i) and (ii).

We additionally note that HHS no longer collects charges or makes payments to issuers for the temporary Federal risk corridors program established in section 1342 of the ACA, which expired after the 2016 benefit year, and that therefore, the policy goal of aligning similar components in the risk corridors and MLR calculation no longer exists.²⁵³ We have provided guidance to issuers regarding the reporting of risk corridors amounts for the applicable reporting years through MLR Reporting Instructions and other guidance, most recently on December 30, 2020.²⁵⁴ While we recognize that the MLR and rebate calculation methodology finalized in the 2014

Payment Notice used the same variables to account for risk adjustment and risk corridors payments and risk adjustment and risk corridors charges, we do not believe that it is necessary to amend the regulations at §§ 158.130, 158.221(c), and 158.240(c) to modify the treatment of the Federal risk corridors amounts that are no longer being paid or collected. In addition, for consistency with the statutory language and our maintenance of the references to Federal transitional reinsurance amounts, we are similarly retaining the references to risk corridors in the formula for the MLR calculation.

In sum, we propose that for qualifying issuers, risk adjustment transfer amounts would be a net adjustment to the denominator, rather than the numerator, of the MLR calculation as follows:

$$\text{If } (ra/p) > \text{or} = 50\%; \\ \text{Adjusted MLR} = [(i + q - s + nc - rc) / \{ (p + s - nc + rc) - t - f - (s - nc + rc) - na + ra \}] + c$$

Where,

i = incurred claims

q = expenditures on quality improving activities

p = earned premiums

t = Federal and State taxes

f = licensing and regulatory fees including transitional reinsurance contributions

s = issuer’s transitional reinsurance receipts

na = issuer’s risk adjustment related payments

nc = issuer’s risk corridors related payments

ra = issuer’s risk adjustment related receipts

rc = issuer’s risk corridors related receipts

c = credibility adjustment, if any

For a qualifying issuer whose MLR falls below the minimum MLR standard in a State and market, we propose to calculate the MLR rebate in § 158.240(c) as follows:

$$\text{If } (ra/p) > \text{or} = 50\%; \\ \text{Rebates} = (m - a) * [(p + s - nc + rc) - t - f - (s - nc + rc) - na + ra]$$

Where:

m = the applicable minimum MLR standard for a particular State and market

a = issuer’s MLR for a particular State and market.

We note that, under this proposal, the proposed alternate MLR and rebate methodologies would only apply to qualifying issuers. For all other issuers, the current MLR and rebate methodologies codified at § 158.140 and § 158.240 would continue to apply. We propose that these amendments would be applicable beginning with the 2026 MLR reporting year (MLR reports due in 2027), in order to enable issuers that are or may be able to meet the definition of qualifying issuer to reflect the amendments in their premium rates.

²⁵¹ See 45 CFR 158.221. See also the Transparency in Coverage Final Rule, 85 FR 72158, 72246 (Nov. 12, 2020).

²⁵² See Transitional Reinsurance Program Payment Audits, available at: <https://www.cms.gov/center-consumer-information-and-insurance-oversight>.

²⁵³ On April 27, 2020, the Supreme Court ruled in *Maine Community Health Options v. United States*, 140 S. Ct. 1308 (2020), 590 U.S. (2020), that section 1342 of the ACA created an enforceable government obligation to pay risk corridors amounts as calculated under the risk corridors formula. Since that time, the United States has made payments from the Judgment Fund to issuers for their previously unpaid risk corridors amounts.

²⁵⁴ See CMS. (2020, December 30). Insurance Standards Bulletin Series—Treatment of Risk Corridors Recovery Payments in the Medical Loss Ratio and Rebate Calculations. <https://www.cms.gov/files/document/mlr-guidance-rc-recoveries-and-mlr-final.pdf>.

We request comment on all aspects of this proposal. Specifically, we request comment on the definition of “qualifying issuer,” and whether issuers should satisfy additional criteria to qualify for this flexibility. We also request comment on whether the proposed alternate MLR and rebate methodologies that would apply to qualifying issuers would create any inappropriate incentives for issuers that are unable to accurately price their products or reduce administrative costs. Finally, we request comment on impacts to other issuers that are not “qualifying issuers” and potential market distortions that may arise if the proposed flexibility for MLR and rebate calculations is not extended to all issuers in applicable markets.

We are also considering an alternative approach that would modify § 158.140(b)(4)(ii) to no longer apply net risk adjustment receipts as an adjustment to the incurred claims amount that is used to calculate the MLR numerator defined in § 158.221(b) for all issuers subject to MLR requirements, which, as noted above, we believe to be consistent with the construction of the MLR formula in section 2718 of the PHS Act. Under this alternative approach, we would not make any changes to the definition of premium revenue in § 158.130, or to the regulatory treatment of Federal reinsurance or risk corridors in the MLR formula. Similar to the proposal above, under this alternative approach, we would modify the calculation of the MLR denominator and rebates as described in the 2014 Payment Notice such that for all issuers, earned premium would account for net risk adjustment receipts by simply adding these net receipts to total premium, without subsequently subtracting them from adjusted earned premium. The effect of this alternative approach would be that risk adjustment transfer amounts would have a net impact on the MLR denominator and rebate calculations in § 158.221(c) and § 158.240(c), respectively. This alternative approach would allow us to streamline MLR reporting in light of the expiration of the risk corridors program after the 2016 benefit year. In addition, this alternative approach would align MLR with the accounting approach used for risk adjustment transfers in State financial reporting, which accounts for these amounts in premium.²⁵⁵

Under this alternative approach, risk adjustment transfer amounts would be a net adjustment to the denominator,

rather than the numerator, of the MLR calculation, for all issuers, as follows:

$$\text{Adjusted MLR} = [(i + q - s + nc - rc) / \{(p + s - nc + rc) - t - f - (s - nc + rc) - na + ra\}] + c$$

Where,

i = incurred claims

q = expenditures on quality improving activities

p = earned premiums

t = Federal and State taxes

f = licensing and regulatory fees including transitional reinsurance contributions

s = issuer's transitional reinsurance receipts

na = issuer's risk adjustment related payments

nc = issuer's risk corridors related payments

ra = issuer's risk adjustment related receipts

rc = issuer's risk corridors related receipts

c = credibility adjustment, if any

For an issuer whose MLR falls below the minimum MLR standard in a State and market, we would calculate the MLR rebate in § 158.240(c) as follows:

$$\text{Rebates} = (m - a) * [(p + s - nc + rc) - t - f - (s - nc + rc) - na + ra]$$

Where,

m = the applicable minimum MLR standard for a particular State and market

a = issuer's MLR for a particular State and market.

We believe that both the proposal and the alternative approach present a valid means of accounting for the impact of premium stabilization program amounts in the MLR and rebate calculations. Because most issuers are above the threshold for paying MLR rebates, we do not believe that the alternative approach would materially impact rebate payments for most issuers. However, for some issuers that are either below or close to the MLR standard, the alternative approach could result in larger rebate payments, particularly for issuers that owe risk adjustment charges and that have plan designs that result in premiums that are lower than the market average. We recognize the possibility that some of these issuers may further adjust premiums in response to this alternative approach if it were finalized. We are not proposing this alternative approach as we believe that the more narrow, tailored proposal to provide this flexibility only for qualifying issuers is sufficient to maximize availability of coverage options while remaining consistent with the statutory objective of section 2718 of the PHS Act, which is to ensure that consumers receive value for their premium dollars. The more narrow, tailored proposal would also produce a smaller reduction in rebate payments to consumers than the alternative approach and would cause less disruption to the industry.

We request comment on all aspects of this alternative approach, including on ways that this alternative approach could potentially influence issuers' rebate positions, plan composition, and pricing decisions. Finally, we request comment on potential impacts of this alternative approach on consumers.

F. Severability

As demonstrated by the number of distinct programs addressed in this rulemaking and the structure of this proposed rule in addressing them independently, HHS generally intends the rule's provisions as finalized to be severable from each other. For example, the proposed rule outlines proposed payment parameters and provisions for the HHS-operated risk adjustment and data validation programs, 2026 user fee rates for issuers in these programs, and changes to the BHP payment calculations. It includes proposed modifications to the initial and second validation audit processes and addresses HHS' authority to take enforcement action against lead agents at insurance agencies for violations of HHS' Exchange standards and requirements. The rule also addresses certification standards, ECP reviews, public sharing of aggregated, summary-level QIS information on an annual basis, and proposed revisions to the MLR reporting and rebate requirements for qualifying issuers that meet certain standards. It is HHS' intent that if any provision of these proposed rules, if finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, the rule shall be construed so as to continue to give maximum effect as permitted by law, unless the holding shall be one of utter invalidity or unenforceability. In the event a provision as finalized is found to be utterly invalid or unenforceable, HHS intends that that provision to be severable.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of the agency.

²⁵⁵ See, for example, NAIC, Supplemental Health Care Exhibit Instructions for Part 2, Line 1.1.

- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. Wage Estimates

To derive wage estimates, we generally use data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for the cost of fringe benefits and overhead) for estimating the burden associated with the ICRs.²⁵⁶ Table 14 presents the median hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 14: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Median Hourly Wage (\$/hr.)	Fringe Benefits and Overhead (\$/hr.)	Adjusted Hourly Wage (\$/hr.)
Business Operations Specialists, All Other	13-1199	38.26	38.26	76.52
Health Information Technologists and Medical Registrars	29-9021	30.28	30.28	60.56
Compliance Officer	13-1041	36.38	36.38	72.76

B. ICRs Regarding the Initial Validation Audit (IVA) Sample—Enrollees Without HCCs, Removal of the FPC, and Neyman Allocation (§ 153.630(b))

Beginning with the 2025 benefit year of HHS–RADV, we propose to exclude enrollees without HCCs from the IVA sampling methodology, to remove the FPC from IVA sampling,²⁵⁷ and to replace the source of the Neyman allocation data with the most recent 3 years of consecutive HHS–RADV data with results that have been released before HHS–RADV activities for the benefit year begin. Specifically, these proposals would exclude enrollees without HCCs (stratum 10 enrollees that do not have HCCs nor RXCs and RXC-only enrollees in strata 1 through 3) from IVA sampling, remove the FPC such that issuers with 200 or more enrollees in strata 1 through 9 would have IVA sample sizes of 200 enrollees and issuers with less than 200 enrollees in strata 1 through 9 would have IVA sample sizes equal to their population of enrollees with HCCs, and change the source of the Neyman allocation data used to calculate the standard deviation of risk score error from MA–RADV data to HHS–RADV data. By removing

enrollees without HCCs from IVA sampling, the Neyman allocation would only apply to enrollees with HCCs in strata 1 through 9 in the IVA sample.

These proposals are intended to improve the validity of our IVA sampling assumptions and sampling precision and would decrease burden on issuers when implemented in combination. As noted in section III.B.6 of this rule, the proposed changes to the IVA sampling methodology would result in increased sample sizes for some smaller issuers that are subject to the FPC and assigned IVA sample sizes less than 200 enrollees under the current methodology. However, sample size is not necessarily indicative of issuer burden in HHS–RADV, as the driving factor of burden is the number of enrollee medical records that must be retrieved and reviewed for the IVA sample. Overall, the proposed IVA sampling methodology in this rule alters the allocation of strata sample sizes within the IVA sample, ultimately resulting in relatively fewer enrollees from medium or high-risk strata, who have more medical records to review, being selected for the IVA sample. Consequently, under these proposed

changes, the average number of medical records reviewed per enrollee in the IVA sample and the total number of medical records reviewed per issuer would decrease.

The currently approved information collection (OMB Control Number 0938–1155/Expiration April 30, 2025) for conducting the IVA takes into account that the issuer must review the IVA sample and determine which enrollees will require medical records to validate their HCCs and details the processes the issuer must undertake to obtain medical records for their enrollees selected for the IVA sample. In the currently approved information collection, we estimate an upper limit of 650 issuers submitting samples of 200 enrollees for HHS–RADV for any given benefit year, five medical record requests per enrollee in the IVA sample size and three HCCs to be reviewed by a certified medical coder per enrollees with HCCs, which leads to an aggregate burden of conducting IVAs of approximately 1,663,729 hours and \$116,963,821.²⁵⁸ Given the changes to the IVA sample under the proposed policies in this rule and recent HHS–RADV data, we estimate an upper limit of 600 issuers

²⁵⁶ See Department of Labor. (2024, April 3). Bureau of Labor Statistics, Occupational Employment and Wage Statistics, May 2023 Occupation Profiles. https://www.bls.gov/oes/current/oes_stru.htm.

²⁵⁷ In the current IVA sampling methodology, a Finite Population Correction factor is used to calculate a target IVA sample size less than 200 enrollees for issuers with less than 4,000 enrollees.

²⁵⁸ OMB Control No: 0938–1155 (exp. April 30, 2025). https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202308-0938-015.

submitting samples of 200 enrollees for HHS–RADV for any given benefit year.²⁵⁹ We estimate an approximate average of two medical records reviewed and two HCCs reviewed per enrollee in the IVA sample.

For our monetary and hourly burden estimates, we are incorporating labor and wage costs from the most recent premium stabilization programs information collection, “Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals” (OMB Control Number 0938–1155/Expiration April 30, 2025). Based on an analysis that applies the proposed changes to remove enrollees without HCCs from IVA sampling, remove the FPC, and use HHS–RADV data in the Neyman allocation beginning with 2025 benefit year HHS–RADV, approximately 200 enrollees in an issuer sample will require medical records to validate HCCs, with approximately two medical record requests per enrollee (approximately 400 medical record requests per issuer) if these policies are finalized as proposed.²⁶⁰ We estimate it will take a business operations specialist (occupation title “Business Operations Specialists, All Other” at an hourly wage rate of \$76.52) approximately 1 hour to complete, review, and conduct follow-up on each medical record request (20 minutes each to complete each medical record request, review the response to each medical record request, and to conduct further follow-up on each medical record request). For each issuer, we anticipate the burden would be approximately 400 hours at a cost of \$30,608. For an estimated 600 issuers required to submit samples for HHS–RADV for any given benefit year, we

anticipate that the aggregate burden of completing medical record reviews will be approximately 240,000 hours and \$18,364,800.

Based on a review of enrollee-level EDGE data for the 2017–2021 benefit years and the proposed changes to the IVA sampling methodology in this rule, we have determined that for enrollee with HCCs, the average number of HCCs to be reviewed by a certified medical coder per enrollee would be approximately two HCCs if these policies are finalized as proposed. Additionally, based on HHS–RADV audit experience, we estimate that it may cost approximately \$272.52 (\$60.56 per hour for 4.5 hours on average) for a certified medical coder to review the medical record documentation for one enrollee with roughly two HCCs. For 200 enrollees with HCCs in an issuer’s IVA sample, the total cost to each issuer would be \$54,504 (for 900 hours). In some cases, a secondary review by a senior certified medical coder (occupation title “Health Information Technologists and Medical Registrars” at an hourly wage rate of \$60.56 per hour) will be needed to re-review approximately one-third of the medical record documentation required during the first review. Thus, a senior certified medical coder would need to review medical documentation for the equivalent of approximately 66 enrollees with HCCs in an issuer sample. We estimate that the total cost to each issuer would be approximately \$17,986.32 (\$60.56 per hour for 4.5 hours per enrollee). For this review and secondary review, the total cost to each issuer would be approximately \$72,490.32 (1,197 total hours).

These proposals will not affect the review of demographic and enrollment information, as we will continue to validate demographic and enrollment information for a subsample of up to 50 enrollees from the audit sample, or the RXC review, as the audit entity must review RXCs for all adult enrollees in the audit sample with at least one RXC, and we continue to assume that an IVA will be performed on approximately 50 RXCs per issuer. As such, we are only changing our burden estimates of demographic and enrollment or RXC review to update the most recent BLS’ median hourly wage estimates. We estimate that it may cost approximately \$20.19 per enrollee (\$60.56 per hour for 20 minutes) to validate demographic information for 50 enrollees in each audit sample totaling \$1,009.33 per issuer. Similarly, we estimate that RXC validation for 50 enrollees would cost approximately \$20.19 per RXC (\$60.56 per hour for 20 minutes), totaling

\$1,009.33 per issuer. In addition, for each issuer, we expect it would require a compliance officer working 40 hours at \$72.76 per hour, and 2 operations managers working a total of 80 hours at \$97.38 per hour to make available to external medical coders associated with the initial validation audit entity claims documents for review of demographic information and RXC review (120 hours at a combined cost of \$10,701).

For each issuer submitting audit findings for HHS–RADV in a given benefit year, the total burden for reporting, coding, and administration would be approximately 1,750.33 hours at a cost of \$115,817.79 per issuer. For an estimated 600 issuers required to submit audit findings for HHS–RADV for any given benefit year, we anticipate that the aggregate burden of conducting IVAs will be approximately 1,050,200 hours and \$69,490,672 beginning in 2025. This reflects an aggregate burden decrease of 613,529 hours and \$47,473,149 from the existing aggregate burden estimate of approximately 1,663,729 hours and \$116,963,821.

We seek comment on this proposal and the estimated burdens discussed above.

C. ICRs Regarding Engaging in Compliance Reviews and Taking Enforcement Actions Against Lead Agents for Insurance Agencies (§ 155.220)

This proposal addresses HHS’ authority to engage in compliance reviews of and take enforcement action against lead agents of insurance agencies in both FFE and SBE–FP States for misconduct or noncompliant activity at the agency level. We are not proposing any changes to regulations as the current regulatory framework and definitions supports this approach. Furthermore, this proposal only envisions collecting agency-level documentation, including but not limited to, training manuals, onboarding material, and marketing materials, from lead agents, in addition to the existing documentation collection²⁶¹ for agents, brokers, or web-brokers, to investigate potential misconduct or noncompliant behavior or activities. Therefore, this collection would fall under 5 CFR 1320.4(a)(2), stating collections of information “. . . during the conduct of an [. . .] investigation” are exceptions

²⁵⁹ A total of 605 issuers participated in the HHS-operated risk adjustment program for the 2023 benefit year. However, some of these issuers are subject to exemptions from HHS–RADV under 45 CFR 153.630(g) and would not submit IVA samples for HHS–RADV. For example, any issuers at or below the materiality threshold for random and targeted sampling only participate in HHS–RADV approximately once every 3 years. Therefore, we use 600 issuers as a conservative upper limit of the number of issuers that could participate in a given benefit year of HHS–RADV. See the Summary Report on Individual and Small Group Market Risk Adjustment Transfers for the 2023 Benefit Year (July 22, 2024) available at: <https://www.cms.gov/ccio/programs-and-initiatives/premium-stabilization-programs/downloads/ra-report-by2023pdf>.

²⁶⁰ This estimate is a decrease from the previous estimate of medical record requests per enrollee because the proposed changes to the IVA sampling methodology in the 2026 Payment Notice, if finalized as proposed, would generally result in relatively fewer enrollees sampled from medium- and higher-risk strata, which are generally composed of enrollees with more medical records whereby reducing our estimated number of medical records for review.

²⁶¹ This includes documentation of consumer review and confirmation of the accuracy of eligibility application information in compliance with 45 CFR 155.220(j)(2)(ii)(A)(2) and consumer consent documentation in compliance with 45 CFR 155.220(j)(2)(iii)(c).

to the ICR requirements.²⁶² The documentation that will be collected will solely relate to investigations of potential misconduct or noncompliant behavior or activities such that this exception would apply.

We seek comment on these assumptions.

D. ICRs Regarding Agent and Broker System Suspension Authority (§ 155.220(k))

This proposal would expand HHS' authority to suspend Exchange system access for agents and brokers under § 155.220(k)(3) to also include situations that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations or Exchange applicants or enrollees, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. Since this proposal would entail providing an opportunity for agents and brokers to submit evidence and information to demonstrate that the circumstances of the incident, breach, or noncompliance has been remedied or sufficiently mitigated to HHS' satisfaction, it would involve collecting documents from agents and brokers whose system access has been suspended. Depending on the circumstances leading to the system suspension, we anticipate receiving documentation of consumer consent and/or review and confirmation of the accuracy of the Exchange eligibility application information and assessing whether the documentation complies with § 155.220(j)(2)(ii) and (iii) for consumers cited in the suspension notice from agents and brokers we system suspend under § 155.220(k)(3). The system suspension authority in § 155.220(k)(3) is part of HHS' oversight and enforcement framework applicable to agents and brokers who participate in the FFEs and SBE-FPs. Therefore, this collection would fall under 5 CFR 1320.4(a)(2), stating collections of information “. . . during the conduct of an [. . .] investigation” are exceptions to the ICR requirements.²⁶³ The documentation that would be collected would solely relate to investigations and responses to system suspensions, meaning this exception would apply.

We seek comment on these assumptions.

E. ICRs Regarding Updating the Model Consent Form (§ 155.220)

We are proposing amendments to the Model Consent Form created as part of the 2024 Payment Notice (88 FR 25809 through 25811). The existing Model Consent Form only provides a template for meeting the consent documentation and retention requirements of § 155.220(j)(2)(iii)(A)-(C). We are proposing to update that Model Consent Form to also include a template to meet the requirements under § 155.220(j)(2)(ii), which requires agents, brokers, and web-brokers to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative prior to submission of the application to the FFE or SBE-FP. This proposal would only update the optional Model Consent Form that was created as part of the 2024 Payment Notice and adopted on June 30, 2023. The 2024 Payment Notice²⁶⁴ considered the additional time it would take the assisting agent, broker, or web-broker to process and submit each consumer's eligibility application and those assumptions remain valid and are unchanged. We believe these assumptions remain as none of the regulatory requirements established by the 2024 Payment Notice are being changed and no new requirements are being added with this proposal. Therefore, this proposal would not impart extra time or costs to the assisting agent, broker, or web-broker. Agents, brokers, and web-brokers are already required to meet the requirements of § 155.220(j)(2)(ii) and (iii), meaning the time required to gather the documentation required by the 2024 Payment Notice requirements is already a part of every agent's, broker's, and web-broker's enrollment process. We do not believe the updated Model Consent Form would impose any additional burden on agents, brokers, web-brokers, or consumers, because usage of this Model Consent Form remains optional and this updated Model Consent Form is simply intended to provide a useable example of how agents, brokers, agencies and web-brokers may compliantly meet the documentation requirements already required by the 2024 Payment Notice. If agents, brokers, agencies or web-brokers elect to use this form, we do not anticipate that the updated Model Consent Form would take any longer to fill out than agent, broker, web-broker, or agency-created forms or other methods being already

being utilized currently as the requirements for documentation are not changing from the documentation requirements that agents, brokers, agencies and web-brokers are already required to meet in their current agent, broker, web-broker or agency created forms or methods.

The proposed Model Consent Form would also include scripts agents, brokers, or web-brokers could utilize to meet the consumer consent and eligibility application review requirements finalized in the 2024 Payment Notice requirements when assisting consumers via an audio recording. The scripts would ensure agents, brokers, or web-brokers having verbal, recorded conversations with consumers discuss all the regulatory requirements with consumers. We do not anticipate these scripts would increase burden on any assisting agent, broker, web-broker or consumer as no regulatory requirements have been changed. As agents, brokers, and web-brokers should already be complying with these requirements, no additional costs would be borne by the agent, broker, or web-broker if using the updated Model Consent Form scripts. The scripts are merely meant to provide agents, brokers, and web-brokers guidance and clarification on how the consent documentation and eligibility application review documentation requirements can be met when having a verbal, recorded conversation with a consumer. The proposed scripts in the updated Model Consent Form are not mandatory and are not intended to limit or otherwise impact the agent, broker, or web-broker's ability to answer consumer questions about plan selection or other matters.

Finally, there is no anticipated increase in documentation collection burden on HHS based on the updated model consent form. We currently request documentation of consumer consent and eligibility application review for compliance reviews and, assuming agents, brokers, and web-brokers used the updated model consent form, that would not meaningfully impact the documentation collection or review by HHS.

If this proposal is finalized, the updated Model Consent Form discussed in this section would be submitted for OMB review and approval in the amended PRA package (OMB Control Number 0938-1438/Expiration date: June 30, 2026). We seek comment on these assumptions.

²⁶² 5 CFR 1320.4(a)(2).

²⁶³ 5 CFR 1320.4(a)(2).

²⁶⁴ 88 FR 25890 through 25891.

F. ICRs Regarding Notification of Two Year Failure To File and Reconcile Population (§ 155.305)

We are proposing to amend current regulation at § 155.305(f)(4) under which an Exchange needs to provide notification to either an enrollee or their tax filer (or both) who have been identified as having failed to file their Federal income taxes and reconcile their APTC after two consecutive tax years. This provision is not associated with an ICR under 5 CFR 1320.3(c) and not subject to the requirements of the PRA. We anticipate that the proposed amendment will not impact the information collection (OMB Control Number 0938–1207) burden for Exchanges.

G. ICRs Regarding General Program Integrity and Oversight Requirements (§ 155.1200)

As discussed in the preamble of this rule, we intend to increase transparency into Exchange operations by publishing annual State Exchange and SBE–FP SMARTs, programmatic and financial audits, Blueprint applications, and additional data points in the Open Enrollment (OE) data reports. We estimate that there will be no additional costs or burdens on Exchanges associated with this proposal since this data is already collected through the Blueprint application (OMB Control Number: 0938–1172), SMART (OMB Control Number: 0938–1244), and Enrollment Metrics PRA (OMB Control Number: 0938–1119).

H. ICRs Regarding Essential Community Provider Certification Reviews (§ 156.235)

The proposal to conduct ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions effective beginning in PY 2026 continues our ECP data collection as permitted under the currently approved information collection (OMB Control Number: 0938–1187/Expiration date: June 30, 2025).

To satisfy the ECP requirement under § 156.235, medical QHP and SADP issuers must complete and submit ECP data as part of their QHP application, in which they must list the names and geographic locations of ECPs with whom they have contracted to provide health care services to low-income, medically underserved individuals in their service areas. These issuers must contract with a certain percentage, as determined by HHS, of the available ECPs in the plan's service area. This proposal, if finalized, would not significantly change the burden currently approved under OMB Control Number 0938–1415,²⁶⁵ because the ECP data collected remains the same. Only the format in which the ECP information is submitted would be different. As described in the preamble, issuers in FFEs, including in States performing plan management functions, can now submit ECP data to HHS via MPMS. As a result of HHS system design enhancements via MPMS, HHS is now able to collect ECP data directly from issuers in FFEs in States performing plan management functions,

enabling HHS to conduct independent ECP evaluations of each issuers' network.

I. ICRs Regarding Quality Improvement Strategy Information (§ 156.1130)

There is no information collection associated with this proposal and no changes are proposed to the QIS data collection requirements applicable to QHP issuers. QIS data collection from QHP issuers to the Exchange has been approved under OMB Control Number 0938–1286.

J. ICRs Regarding Medical Loss Ratio (§§ 158.103, 158.140, 158.240)

We propose to add a definition of “qualifying issuer” to § 158.103, amend § 158.140(b)(4)(ii) to no longer adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes for qualifying issuers, make conforming amendments to the rebate calculation example in § 158.240(c)(2), and add § 158.240(c)(3) to provide a rebate calculation example for qualifying issuers. To the extent issuers currently report their risk adjustment transfer amounts on their Annual MLR Reporting Form(s), we do not expect there to be any impact on the reporting burden, as the affected issuers would continue to report the same risk adjustment transfer amounts but would include them on different lines of the MLR Annual Reporting Form. The burden related to this information collection is currently approved under OMB Control Number: 0938–1164.

K. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 15: Proposed Annual Recordkeeping and Reporting Requirements

Regulation Section(s)	OMB Control Number	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$)	Total Cost (\$)
45 CFR 153.630(b)	0938-1155	600	600	-1,022.55	-613,529	-\$47,473,149	-\$47,473,149
TOTAL		600	600		-613,529	-\$47,473,149	-\$47,473,149

L. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These

requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS' website www.cms.hhs.gov/PaperworkReductionActof1995, or call

the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule

²⁶⁵ OMB Control Number 0938–1415: Essential Community Provider-Network Adequacy (ECP/NA)

Data Collection to Support QHP Certification (CMS–10803).

and identify the rule [CMS–9888–P], the ICR’s CFR citation, CMS ID number, and OMB Control Number.

ICR-related comments are due [DATE].

M. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule includes payment parameters and provisions related to the HHS-operated risk adjustment and risk adjustment data validation programs, as well as 2026 user fee rates for issuers offering QHPs through FFEs and SBE-FPs. This proposed rule also includes proposed requirements related to modifications to the calculation of the BHP payment, changes to the IVA sampling approach and SVA pairwise means test for HHS–RADV, as well as proposed compliance reviews of and enforcement action against lead agents, proposed updates to the Model Consent Form, the authority for HHS to suspend agent and broker access to Exchange systems, consumer notification requirements, and proposed standards for an issuer to request the reconsideration of denial of certification as a QHP specific to the FFEs, proposed changes to the approach for conducting ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions, and proposed revisions to the MLR reporting and rebate requirements for qualifying issuers.

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), Executive Order 14094 entitled “Modernizing Regulatory Review” (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The April 6, 2023 Executive Order on Modernizing Regulatory Review²⁶⁶ amends Section 3(f) of Executive Order 12866 to define a “significant regulatory action” as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of OMB’s Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized

review would meaningfully further the President’s priorities or the principles set forth in the Executive Order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for significant rules. OMB’s OIRA has determined that this rulemaking is “significant” as measured by the \$200 million threshold under section 3(f)(1). We have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

As required by OMB Circular A–4 (available at <https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf>), we have prepared an accounting statement in table 16 showing the classification of the impact associated with the provisions of this proposed rule.

This proposed rule implements standards for programs that would 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 Exchanges. We are unable to quantify all the benefits and costs of this proposed rule. The effects in table 16 reflect qualitative assessment of impacts and estimated direct monetary costs and transfers resulting from the provisions of this proposed rule for health insurance issuers and consumers. The annual monetized transfers described in table 17 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers.

²⁶⁶ Office of the White House. (2023, April 6). *Executive Order on Modernizing Regulatory Review*. <https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/06/executive-order-on-modernizing-regulatory-review/>.

TABLE 16: Accounting Table

Benefits:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	\$39 million	2024	2 percent	2025-2029
Quantitative: - Cost savings of \$47,473,149 annually for issuers for conducting IVAs due to IVA sampling methodology changes reducing the estimated number of medical records for review beginning with the 2025 benefit year of HHS-RADV. - Total cost savings of \$1,884,632.40 annually for the 12 FFE States currently performing plan management functions associated with reduced administrative burden as proposed since they would no longer be responsible for ECP data review. - Reduced Federal costs by approximately \$75,000 per year and administrative burden associated with the HHS-RADV materiality threshold proposal, as this proposal would eliminate situations wherein HHS is required to reissue HHS-RADV for all issuers when the impact is less than \$10,000 beginning in 2025.				
Qualitative: - Decreased risk of adverse selection with respect to coverage of PrEP users, resulting in an increase in health equity among this population due to the proposal to incorporate PrEP in HHS risk adjustment adult and child models, as a new, separate type of model factor. - Improved education of tax filers and enrollees regarding the new two-tax year FTR requirements. - Improved processing by State Exchanges of enrollment data inaccuracies, which benefits consumers by ensuring accurate payment of APTCs by proposing to codify HHS' standard for reporting enrollment inaccuracies and for the State Exchange to resolve them. - Reduced enrollment barriers, particularly for low-income enrollees who would be disproportionately impacted by disruptions in coverage, associated with the proposal to allow issuers to implement a fixed-dollar premium payment threshold. - Increased compliance with AV de minimis ranges associated with the approach to release the AV Calculator earlier. - Increased transparency in Exchanges by publishing annual State Exchange and SBE-FP SMARTs, programmatic and financial audits, Blueprint applications, and additional data points in the OE data reports				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	\$3 million	2024	2 percent	2025-2029
Quantitative: - Cost increase for the medical review by approximately \$1.5 million annually for the Federal government due to initial SVA subsample size increase beginning with the 2024 benefit year of HHS-RADV. - Annual cost increase of \$500,000 to the Federal government for increases to SVA medical record review due to the proposed SVA pairwise means testing procedure resulting in more SVA subsamples being expanded for review beginning with the 2024 benefit year of HHS-RADV. - One-time cost of \$250,000 to the Federal government to code modifications to the existing SVA pairwise means test in the Audit Tool beginning with the 2024 benefit year of HHS-RADV. - Annual costs of \$134,000 to the Federal government to send initial direct FTR notices to the two-tax year FTR population starting in benefit year 2025. - Annual costs of \$31,920 to State Exchanges for FTR notices for the two-tax year population. - Regulatory review costs of \$1,963,438.75 for interested parties to review and analyze this proposed rule.				
Qualitative: Not a significant increase in administrative burden or financial impact on the Federal government for ECP data review due to the proposal to conduct ECP certification reviews for plans offered by issuers in FFEs in States performing plan management functions beginning in PY 2026, due to using existing system infrastructure for the FFEs.				
Transfers:	Estimates	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	Primary: \$1.098 billion	2024	2 percent	2025-25

				2029
	Low: \$909 million	2024	2 percent	2025 - 2029
	High: \$1.186 billion	2024	2 percent	2025 - 2029
Quantitative:				
• An estimated annual transfer of APTC of \$481,477,453.60 from the Federal government to enrollees whose coverage would otherwise be terminated for non-payment as a result of the proposal to establish an optional fixed-dollar premium payment threshold beginning in 2025. • Increase in FFE and SBE-FP user fee transfers from issuers to the Federal government of \$644 million for benefit year 2026 compared to if the user fee level from the prior benefit year were maintained in 2026. We estimate additional increases in FFE and SBE-FP user fee transfers from issuers to the Federal government of \$849 million in 2027, \$852 million in 2028, and \$854 million in 2029 if the proposed 2026 user fee level were maintained in subsequent years. Under the alternate FFE and SBE-FP user fee proposal, which reflects different enrollment assumptions, we estimate increases in FFE and SBE-FP user fee transfers compared to if the 2025 benefit year user fee level were maintained for 2026 and beyond from issuers to the Federal government within a range of \$425 million to \$690 million in 2026, \$585 million to \$950 million in 2027, \$607 million to \$985 million in 2028, and \$629 million to \$1.021 billion in 2029 if user fee rates in the alternate range were maintained in subsequent years. • Annual cost of \$8,155 associated with ECP enforcement action is transferred from the FFEs in States performing plan management functions to the Federal government in accordance with the proposal for HHS to conduct ECP reviews for these States. • Reduced rebates paid by issuers to consumers or increased premiums collected by issuers from consumers of approximately \$20 million annually beginning with the 2026 MLR reporting year associated with the proposal to add a definition of “qualifying issuer” to no longer adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes for qualifying issuers.				

TABLE 17: Estimated Federal Government Outlays and Receipts for the Risk Adjustment and Reinsurance Programs from Fiscal Year 2026-2030, in billions of dollars¹

Year	2026	2027	2028	2029	2030	2026-2030
Risk Adjustment and Reinsurance Program Payments	9	10	10	10	10	49
Risk Adjustment and Reinsurance Program Collections	-10	-10	-10	-10	-10	-50

Note: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time. Source: Congressional Budget Office. Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2023 to 2033. Table A-2. September 2023. <https://www.cbo.gov/system/files/2023-09/59273-health-coverage.pdf>.

1. BHP Methodology Regarding the Value of the Premium Adjustment Factor (42 CFR Part 600)

The aggregate economic impact of these proposed changes to the BHP

²⁶⁷ Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments, refunds, and allowable activities.

payment methodology is estimated to be \$0 in transfers for calendar year 2026 and all subsequent years. For the purposes of this analysis, we have assumed that two States would operate BHPs in 2026 since currently only two States operate BHPs, and we do not assume any more States would do so.

For the States currently operating BHPs, we do not anticipate these proposed changes to the payment methodology would affect future payments. We expect that these States would have fully implemented programs by 2026, and thus these proposed changes would not change the value of the PAF used in the payment

methodologies for these States in 2026 and beyond. If other States implemented a BHP and did so on a partial basis, the proposed changes would be expected to reduce Federal BHP payments compared to what they would be under current law. The changes in payments would depend on the number of people on BHP in the State, the QHP premiums in the State, and the level of adjustments added to the premiums to account for the CSRs.

2. Incorporation of PrEP Affiliated Cost Factor (ACF) in the HHS Risk Adjustment Adult and Child Models (§ 153.320)

We are proposing the incorporation of PrEP into the HHS risk adjustment adult and child models as part of a new proposed class of factors that reflect the costs associated with care that is not related to active medical conditions. This proposed class of factors, called the Affiliated Cost Factors (ACFs), which are detailed in the preamble discussion under 45 CFR part 153, will not result in any additional reporting burden for issuers. Because it will have some impact on risk adjustment State transfers, some issuers' State transfers will be impacted, either in a positive or in a negative manner, consistent with the budget-neutral nature of the HHS-operated risk adjustment program. As HHS is responsible for operating the risk adjustment program in all 50 States and the District of Columbia, we do not expect these policies to place any additional burden on State governments. The proposed model specifications 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. This proposal will help mitigate risk of adverse selection for coverage of PrEP users, resulting in increased health equity among this population.

3. Initial Validation Audit (IVA) Sampling Methodology Changes (§ 153.630(b))

Under § 153.630(b), we are proposing several changes to the IVA sampling methodology. Beginning with the 2025 benefit year of HHS–RADV, we propose to exclude enrollees without HCCs (enrollees in stratum 10 without HCCs nor RXCs and RXC-only enrollees in strata 1 through 3) from IVA sampling, remove the FPC such that issuers with 200 or more enrollees in strata 1 through 9 would have IVA sample sizes of 200 enrollees and issuers with less than 200 enrollees in strata 1 through 9 would

have IVA sample sizes equal to their EDGE population of enrollees with HCCs, and change the source of the Neyman allocation data used to calculate the standard deviation of risk score error from MA–RADV data to the 3 most recent consecutive years of HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin, beginning with benefit year 2025 HHS–RADV.

Although issuers are already required to provide the IVA Entities with all documentation necessary to complete HHS–RADV, the proposed changes to the IVA sample would ensure all enrollees in the IVA sample have at least one HCC on EDGE and therefore would have associated medical records that would need to be submitted. In the Collection of Information section of this proposed rule, we estimate the decrease in administrative burden that would result from the proposals to modify the IVA sample as the average number of medical records reviewed per enrollee in the IVA sample and the average number of medical records reviewed per issuer would decrease. We estimate that the aggregate burden of conducting IVAs would be approximately 1,050,200 hours and \$69,490,672 beginning with 2025 benefit year HHS–RADV, which is an aggregate burden decrease of 613,529 hours and \$47,473,149 from the existing aggregate burden estimate of approximately 1,663,729 hours and \$116,963,821. We believe that these proposed changes to the IVA sampling methodology would result in more precise HHS–RADV results which are used to adjust risk scores and associated risk adjustment State transfers. While this could affect the adjustments to risk adjustment State transfers for an individual issuer, we do not expect an impact on aggregate risk adjustment State transfer adjustments because of the proposed modifications to the IVA sampling methodology.

4. Second Validation Audit (SVA) Pairwise Means Test (§ 153.630(c))

We propose to modify the pairwise means test to use a 90 percent confidence interval bootstrapping methodology and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV. Because issuers are already required to provide the IVA and SVA Entities with all documentation necessary to complete the audits, the proposed changes to the pairwise means test that would increase the initial SVA subsample size to 24 enrollees and transition to a bootstrapping methodology using a 90 percent confidence interval would not

directly increase burden on issuers. We believe that these proposed changes would increase the burden and costs to the Federal government of conducting the SVA. We estimate that increasing the initial SVA sample size from 12 to 24 enrollees would increase the annual costs of SVA medical review by approximately \$1.5 million and that transitioning from the current t-test pairwise means testing procedure to a bootstrapped procedure would increase the annual cost of SVA medical review by approximately \$500,000 as more issuers would be expanded to larger SVA sample sizes under a more sensitive pairwise means testing procedure. In addition, there would be a one-time cost of approximately \$250,000 to code these modifications to the existing SVA pairwise means test in the Audit Tool. Any increase in SVA costs would increase the costs to the Federal government associated with HHS–RADV program activities, which are covered through the risk adjustment user fees that are charged to issuers. While issuers would indirectly cover these costs through the risk adjustment user fee, we do not anticipate that this policy alone would increase the risk adjustment user fee as the costs are relatively small compared to the entirety of the budget to operate the HHS-operated risk adjustment program. We believe that the benefits from improving the SVA process for validating the IVA results and determining the appropriate audit results to use in error estimation would outweigh the increased costs to the Federal government and better ensure the integrity of the risk adjustment program.

5. Engaging in Compliance Reviews and Taking Enforcement Actions Against Lead Agents for Insurance Agencies (§ 155.220)

As discussed in the preamble to this proposed rule, we address our authority to investigate, engage in compliance reviews of, and take enforcement actions against lead agents of insurance agencies who are engaging in potential misconduct or noncompliant behavior or activities in FFE and SBE–FP States. This would better align our oversight and enforcement approach with how States regulate agencies. This would also ensure enhanced consumer protections from agency-level misconduct or noncompliance facilitated at the agency level, which similarly impacts consumers negatively as misconduct or noncompliance by individual agents, brokers, and web-brokers. This proposal is also designed to reduce consumer harm associated with unauthorized enrollments or bad-

acting agents, brokers, or web-brokers entering incorrect income information on eligibility applications, leading to incorrect APTC calculations. An incorrect APTC amount can result in a consumer having a zero-dollar monthly premium, which may lead to a consumer not knowing they are enrolled or being incorrectly enrolled in an Exchange plan. This generally occurs because the consumer does not receive monthly billing notifications due to the zero-dollar monthly premium. However, once the consumer files their taxes, a reconciliation may reveal the consumer must repay the incorrect APTC amount they were receiving.

This proposal is also designed to reduce consumer harm associated with unauthorized enrollments or unauthorized plan switches which can lead to the consumer receiving a DMI. Upon application submission, certain consumer data is checked against trusted data sources to ensure a match between what is in the application submission and the information HHS receives from the trusted data source(s). If the trusted data source does not have the consumer data or the data is inconsistent with the information provided on the application, a DMI is generated. A non-exhaustive list of DMIs include the Annual Income DMI, Citizenship/Immigration DMI, and American Indian/Alaskan Native Status DMI. Certain DMIs may lead to loss of Exchange coverage, including a Citizenship/Immigration DMI, which occurs when the consumer is unable to verify an eligible citizenship or lawful presence status.

6. Agent and Broker System Suspension Authority (§ 155.220(k))

We believe the impact related to the proposed changes to § 155.220(k)(3) would be positive. The proposed changes would allow HHS to take swift action for misconduct and noncompliance with existing standards and requirements by expanding the bases on which § 155.220(k)(3) system suspensions may be implemented. This proposal would enhance consumer protection and promote program integrity by allowing HHS to immediately suspend an agent's or broker's access to Exchange systems when HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security

standards at § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. This would help reduce future consumer harm by allowing HHS to quickly suspend system access for agents or brokers who are engaged in misconduct or noncompliant behavior that impacts Exchange consumers, operations, and systems. This proposal would also increase transparency by informing agents and brokers of the full suite of HHS enforcement actions that may be leveraged in response to noncompliance or misconduct, which may help curb such activities and behaviors. We do not anticipate negative feedback from the entities impacted by this, such as agents and brokers, as these changes are meant to more quickly system suspend bad-acting agents and brokers. This would help build consumer trust in compliant agents and brokers who work with consumers on the FFEs and SBE-FPs.

7. Updating the Model Consent Form (§ 155.220)

We are proposing to update the Model Consent Form to include a section that agents, brokers, and web-brokers assisting with and facilitating enrollment through FFEs and SBE-FPs or assisting an individual with applying for APTC and CSRs for QHPs can use to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative prior to application submission in a manner that complies with § 155.220(j)(2)(ii)(A)(1)–(2). We are also proposing to update the Model Consent Form to include scripts agents, brokers, and web-brokers could use when meeting the requirements codified at § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A)–(C) via an audio recording.

These proposals would update the optional Model Consent Form that was created as part of the 2024 Payment Notice and adopted on June 18, 2023. The 2024 Payment Notice (88 FR 25890 through 25892) considered the additional time it would take to process and submit each consumer's eligibility application and those assumptions remain and are unchanged. We believe these assumptions remain because we are not changing the regulatory requirements established by the 2024 Payment Notice, and we are not adding requirements with this proposal. The time required to gather the documentation required by the 2024 Payment Notice requirements is already a part of every agent's, broker's, and web-broker's enrollment process. We do

not believe the updated Model Consent Form would impose any additional burden on agents, brokers, web-brokers, or consumers; we do not anticipate that the updated Model Consent Form would take any longer to fill out than agent, broker, web-broker, or agency-created forms already being utilized. The use of the proposed Model Consent Form would not be mandatory. Therefore, the proposal would not impart extra time or costs to the assisting agent or broker.

This updated model consent form, if finalized, would provide agents, brokers, and web-brokers with clarity on how to meet the regulatory requirements under § 155.220(j)(2)(ii) and help them comply with this regulation by providing a standardized form they may use to do so. Furthermore, we believe providing a clearly written Model Consent Form would provide more consumer clarity and assurance that the agent, broker, or web-broker they are working with is complying with § 155.220(j)(2)(ii). The proposed scripts, to the extent they are utilized by agents, brokers, and web-brokers, would help ensure they are following the regulatory requirements when enrolling consumers. We believe this would reduce consumer harm by reducing unauthorized enrollments, which can result in financial harm if a consumer receives an improper APTC amount upon enrollment, and DMIs, which may lead to cancellation of coverage if the DMIs are not resolved in a timely manner. We also believe this proposal would clarify and simplify how regulated entities can meet regulatory requirements.

We seek comment on these assumptions.

8. Requirement for Notification of Tax Filers and Consumers Who Have Failed To File and Reconcile APTC for Two Consecutive Tax Years (§ 155.305)

We anticipate a small financial impact related to our proposed changes at § 155.305(f)(4)(i)(A)(1)–(2). Prior to pausing the FTR process during the COVID-19 public health emergency, Exchanges provided notice to enrollees or their tax filers (or both) who were identified as at risk of losing their APTC due to their failure to file their Federal income taxes and reconcile their APTC using Form 8962 prior to the FTR Recheck process. The 2025 Payment Notice codified the requirement to send notices in the first tax year a tax filer was identified as having FTR status. This proposal would require sending either direct or indirect notices to tax filers and their enrollees when the tax filer is identified as having FTR status for a second consecutive tax year, which

we estimated in the 2024 Payment Notice to represent 20 percent of the total FTR population. We estimate the cost for Exchanges on the Federal platform to provide direct notices that protect Federal tax information to tax filers would be approximately \$134,000 yearly for fiscal years 2025 through 2029, although there is potential for future growth in the outyears based on increases in the cost of postage and inflation in future years. However, the Departments are not publishing specific future contract estimates in this rule in response to commenters' requests for more detail on estimated expenditures of Federal notice printing activities and the data underlying those estimates because publishing those contract estimates could undermine future contract procurements. For example, if the Department was to publish the projected future cost of the contracts used to provide print notifications, the Federal government would be meaningfully disadvantaged in future contract negotiations related to Federal notice printing activities, as bidders would know how much the Department anticipates such a future contract being worth. Although current contract awards are published and publicly available,²⁶⁸ these award amounts do not necessarily reflect the future value of the contract, as there may be future changes in policy and operations and the scope of the work. Our proposed regulations, if finalized, would give flexibility to Exchanges to choose to send the required notices to enrollees or tax filers, or both. Given the uncertainty about how State Exchanges would choose to provide notices to their enrollees as well as the proportion of enrollees on State Exchanges who fail to file their Federal income taxes and reconcile their APTC for two consecutive tax years, we are unable to provide exact estimates of the cost of providing these notices. We believe that if State Exchanges chose to provide direct mailing notices, the approximate cost could be \$0.84 per notice for FY 2025 based on the cost for the Exchanges on the Federal platform to send an average notice and would likely grow with postage and inflation costs in future years. We anticipate approximately 38,000 total notices across State Exchanges based on historical FTR data from the Exchanges on the Federal platform, and so in total, the estimated cost to State Exchanges to send these notices would be approximately \$31,920 yearly for fiscal years 2025–2029. However, we think this is likely an overestimate based on

conversations with interested parties because many State Exchanges may prefer to provide indirect notices that can be emailed, which would substantially reduce costs to the State Exchanges. There could be some cost related to creation of the notice, but State Exchanges could also choose to use either the language that Exchanges on the Federal platform already use or the language previously used in FTR notices.

We seek comments on this proposal, including regarding additional costs, burdens, and benefits to issuers, consumers, and Exchanges as a result of this proposal.

9. Timeliness Standard for State Exchanges To Review and Resolve Enrollment Data Inaccuracies (§ 155.400(d)(1))

We propose to add § 155.400(d)(1) to codify HHS' guidance document titled, "Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges Frequently Asked Questions,"²⁶⁹ which provides that, within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in an State Exchange (hereinafter referred to as "State Exchange issuer") that includes a description of an inaccuracy that meets the requirements at § 156.1210(a)–(c) and all the information that the State Exchange requires or requests to properly assess the inaccuracy, the State Exchange must review and resolve the State Exchange issuers' enrollment data inaccuracies and submit to HHS a description of the resolution of any inaccuracies described by the State Exchange issuer that the State Exchange confirms to be inaccuracies in a format and manner specified by HHS. This proposed policy aligns with the existing requirement at § 155.400(d) that a State Exchange must reconcile enrollment information with issuers and HHS no less than on a monthly basis. It also provides certainty for State Exchange issuers by providing a timeline for State Exchanges to act upon an enrollment data inaccuracy submitted to the State Exchange by a State Exchange issuer that meets the requirements at § 156.1210(a)–(c).

We do not believe that the proposed amendment would impose substantial additional costs to HHS, State Exchanges, or State Exchanges issuers

beyond the costs that are already accounted for as part of the existing issuers' enrollment data inaccuracies description process and existing State Exchange enrollment data reconciliation requirements. The existing process already requires State Exchange issuers to submit enrollment inaccuracies and the State Exchanges to resolve those inaccuracies and reconcile enrollment information with both State Issuers and HHS no less than on a monthly basis. We have no reason to believe that codifying a timeliness standard would increase burden.

Furthermore, this proposal to codify a timeliness standard for resolution of enrollment data inaccuracies would clarify to issuers in State Exchanges the process for timely reviewing and resolving enrollment data inaccuracies and would ensure the accurate and timely payment of APTCs as this enrollment data is the basis of APTC payments to State Exchange issuers in the automated PBP system.

Therefore, we anticipate that this proposal would streamline the existing issuers' enrollment data inaccuracies process and benefit consumers by ensuring accurate payment of APTCs.

We seek comment on these impact estimates and assumptions.

10. Establishment of Optional Fixed-Dollar Premium Payment Threshold and Total Premium Threshold (§ 155.400(g))

We anticipate that the proposal to allow issuers to implement a fixed-dollar premium payment threshold, adjusted for inflation, would benefit enrollees who may otherwise have been unable to maintain enrollment due to owing *de minimis* amounts of premium. The proposal would likely be especially beneficial to enrollees who are low income, who might be disproportionately impacted by disruptions in coverage. In addition, we believe that issuers that choose to implement a fixed-dollar premium payment threshold would benefit by being able to continue enrollment for enrollees who owe small amounts of premium. We anticipate that there would be some costs associated with implementing a fixed-dollar threshold for those issuers that chose to do so, as well as State Exchanges that chose to allow issuers to do so. Since the proposal would be optional for issuers to adopt, and some may choose not to adopt a payment threshold at all, it is challenging to quantify the impact on APTC payments. However, assuming a fixed-dollar threshold of \$5 or less, based on PY 2023 counts of 79,612 QHP policies terminated for non-payment where the enrollee had a member

²⁶⁹ CMS. (2024, Aug. 14). *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs)*. <https://www.cms.gov/ccio/programs-and-initiatives/health-insurance-marketplaces/downloads/faqs-SBE-reporting-enrollment-data-inaccuracies.pdf>.

²⁶⁸ Available at sam.gov.

responsibility amount of \$0.01–\$5.00, with an average monthly APTC of \$604.78 per enrollee (for PY 2023), we estimate that this at most would result in \$481,477,453.60 in APTC payments for 10 months that excludes the binder payment and first month of the grace period (which the issuer already received APTC for and wouldn't have to return) that issuers would retain, rather than being returned to the Federal government.²⁷⁰ We seek comment on quantifying a lower limit, and whether there are additional costs for other interested parties that have not been considered here.

11. General Eligibility Appeals Requirements (§ 155.505)

This proposed change would allow application filers to file appeals through the HHS appeals entity or a State Exchange appeals entity on behalf of applicants and enrollees on their Exchange application, streamlining the appeals process and ensuring operational consistency between the FFEs and appeals entities. We do not anticipate any financial impact related to our proposed change at § 155.505(b).

12. Proposed Amendments to Certification Standards for QHPs, Request for the Reconsideration of Denial of Certification, and Non-Certification and Decertification of QHPs (§§ 155.1000 and 155.1090)

We propose to amend § 155.1000 by clarifying that an Exchange may deny certification to any plan that does not meet the general certification criteria at § 155.1000 and amend § 155.1090 with refinements to the standards for the request for the reconsideration of a denial of certification specific to the FFEs. We anticipate no appreciable changes in impact because of these proposals. We expect that the FFE would deny certification to one or fewer certification applications on average each year, so we expect the number of affected entities to be small. In addition, the proposed revisions to §§ 155.1000 and 155.1090 do not substantively alter the responsibilities of affected issuers or the content of reconsideration requests. As a result, there is no material impact on regulated entities because of these proposals.

13. General Program Integrity and Oversight Requirements (§ 155.1200)

As part of § 155.1200, we intend to increase transparency in Exchanges by publishing annual State Exchange and

SBE–FP SMARTs, programmatic and financial audits, Blueprint applications, and additional data points in the Open Enrollment (OE) data reports. We anticipate no appreciable change in impact with this proposal since this data is already collected through the Blueprint application (OMB Control Number: 0938–1172), SMART (OMB Control Number: 0938–1244), and Enrollment Metrics PRA (OMB Control Number: 0938–1119). We expect that this proposal would increase the public's understanding of State Exchanges, promote program improvements, and better evaluate Exchange quality.

14. FFE and SBE–FP User Fee Rates for the 2026 Benefit Year (§ 156.50)

We propose an FFE user fee rate of 2.5 percent of monthly premiums for the 2026 benefit year, which is greater than the FFE user fee rate finalized in the 2025 Payment Notice (89 FR 26336 through 26338) of 1.5 percent of total monthly premiums. We also propose an SBE–FP user fee rate of 2.0 percent for the 2026 benefit year, which is greater than the SBE–FP user fee rate finalized in the 2025 Payment Notice of 1.2 percent of total monthly premiums. As a result, we estimate an increase in FFE and SBE–FP user fee transfers from issuers to the Federal government of \$644 million for benefit year 2026 compared to if the user fee level from the prior benefit year were maintained in 2026. We estimate additional increases in FFE and SBE–FP user fee transfers from issuers to the Federal government of \$849 million in 2027, \$852 million in 2028, and \$854 million in 2029 if the proposed 2026 benefit year user fee level were maintained in subsequent years.

We anticipate that these proposed user fee rates would have upward pressure on premiums compared to the 2025 benefit year. We believe that increasing the user fee rates from the 2025 Payment Notice would provide financial stability to the Exchanges on the Federal platform, ensure continuity of special benefits to issuers, and access to QHP plans for enrollees.

We also propose alternate user fee rate ranges if Congress extends the current or a higher level of enhanced PTC subsidies for the 2026 benefit year by March 31, 2025. We recognize that the expiration of the enhanced PTC subsidies at the end of the 2025 benefit year creates a significant amount of uncertainty in the ACA markets and despite this uncertainty, we maintain our interest in ensuring that we collect user fees at a rate that will allow us to sustain the operations of the FFEs.

Therefore, if the enhanced PTC subsidies as currently enacted or higher are extended through the 2026 benefit year by March 31, 2025, we propose a 2026 benefit year FFE user fee rate range between 1.8 and 2.2 percent of total monthly premiums and a 2026 benefit year SBE–FP user fee rate range between 1.4 and 1.8 of total monthly premiums, with each of these ranges to be set at a single rate in the final rule. As a result, if we finalize user fee rates from these ranges, we estimate an increase in FFE and SBE–FP user fee transfers from issuers to the Federal government of between \$425 million to \$690 million for benefit year 2026 compared to if the user fee level from the prior benefit year were maintained in 2026. We estimate additional increases in FFE and SBE–FP user fee transfers from issuers to the Federal government of between \$585 million to \$950 million in 2027, \$607 million to \$985 million in 2028, and \$629 million to \$1.021 billion in 2029 if the alternate proposed 2026 benefit year user fee level were maintained in subsequent years. We seek comment on whether March 31, 2025, provides issuers sufficient time to request rates and for States to review rate requests.

15. Amendments to AV Calculator Update Methodology (§ 156.135)

This approach to revise the method for updating the AV Calculator, starting with the 2026 AV Calculator, resulting in an earlier release of the final AV Calculator for a given plan year, would benefit both issuers and States. Issuers have previously provided feedback that HHS should strive to release the final version of the AV Calculator sooner, and this approach addresses such requests. In addition, States could benefit from an earlier release of the final version of the AV Calculator to ensure their EHB-benchmark plans comply with EHB requirements, and States that design their own standardized plan options could benefit from an earlier release to ensure they satisfy the AV *de minimis* ranges. This approach would have no impact on consumers.

We seek comment on these impact estimates and assumptions.

16. Standardized Plan Options (§ 156.201)

We are proposing minor updates to the standardized plan options for PY 2026 to ensure these plans continue to have AVs within the permissible *de minimis* range for each metal level. We believe maintaining a high degree of continuity in the approach to standardized plan options year over year minimizes the risk of disruption for interested parties, including issuers,

²⁷⁰ See CMS (2024) *Effectuated Enrollment: Early 2024 Snapshot and Full Year 2023 Average*. <https://www.cms.gov/files/document/early-2024-and-full-year-2023-effectuated-enrollment-report.pdf>.

agents, brokers, States, and enrollees. We continue to believe that making major departures from the approach to standardized plan options set forth in the 2023, 2024, and 2025 Payment Notices could result in changes that may cause undue burden for interested parties. For example, if the standardized plan options we create vary significantly from year to year, those enrolled in these plans could experience unexpected financial harm if the cost sharing for services they rely upon differs substantially from the previous year. Ultimately, we believe consistency in standardized plan options is important to allow both issuers and enrollees to become accustomed to these plan designs.

Thus, like the approach taken in the 2023, 2024, and 2025 Payment Notices, we are proposing standardized plan options that continue to resemble the most popular QHP offerings that millions of consumers are already enrolled in. As such, these proposed standardized plan options are based on updated cost sharing and enrollment data to ensure that these plans continue to reflect the most popular offerings in the Exchanges. By proposing an approach to standardized plan options like that taken in the 2023, 2024, and 2025 Payment Notices, issuers would continue to be able to utilize many existing benefit packages, networks, and formularies, including those paired with standardized plan options for PY 2025. Further, issuers would continue to not be required to extend plan offerings beyond their existing service areas.

Furthermore, as discussed earlier in the preamble, we intend to continue to differentially display standardized plan options on *HealthCare.gov* per § 155.205(b)(1). Since we intend to continue to assume responsibility for differentially displaying standardized plan options on *HealthCare.gov*, FFE and SBE-FP issuers would continue to not be subject to this burden. In addition, as noted in the preamble, we intend to continue enforcement of the standardized plan option display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE-FP—the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. We believe that continuing the enforcement of these differential display requirements would not impose a significant burden on these entities or require major modification of their non-Exchange websites, especially since the bulk of this burden was previously imposed in the 2018 Payment Notice,

which finalized the standardized plan option differential display requirements, or during the PY 2023 open enrollment period, when enforcement of these requirements resumed.

Finally, since we intend to continue to allow approved web-brokers and QHP issuers to submit requests to deviate from the manner in which standardized plan options are differentially displayed on *HealthCare.gov*, the burden on these entities would continue to be minimal. We intend to continue providing access to information on standardized plan options to web-brokers through the Health Insurance Marketplace PUFs and QHP Landscape file to further minimize burden by ensuring that affected entities have timely access to accurate and helpful information on standardized plan option requirements, including those related to the differential display of these plans.

We do not anticipate that the proposed modification at § 156.201(c) that would require an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area to meaningfully differentiate these plans from one another in terms of included benefits, networks, and/or formularies would have a significant impact on issuers. This is because most issuers have not offered multiple standardized plan options within the same product network type, metal level, and service area since these requirements were introduced in PY 2023. In fact, current QHP certification submission data indicates that only three issuers intend to offer multiple standardized plan options within the same product network type, metal level, and service area in PY 2025.

However, we acknowledge that those issuers that do offer multiple standardized plan options in the same product network type, metal level, and service area would either have to modify certain offerings (such as by modifying included benefits, provider networks, and/or formularies) or choose to discontinue certain plans to the extent they are not meaningfully different. That said, given that issuers would retain the discretion to choose between modifying or discontinuing plans, and given that making these modifications to plans are a routine part of the annual plan design process, we do not anticipate significant burden for affected issuers related to this proposed requirement.

We seek comment on these impact estimates and assumptions.

17. Non-Standardized Plan Option Limits (§ 156.202)

We propose to amend § 156.202(b) and (d) to properly reflect the flexibility that issuers have been operationally permitted since the introduction of these requirements to vary the inclusion of the distinct adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage categories under the non-standardized plan option limit at § 156.202(b) in accordance with § 156.202(c)(1) through (3).

In particular, we propose to amend § 156.202(b) to properly distinguish between adult dental benefit coverage at § 156.202(c)(1) and pediatric dental benefit coverage at § 156.202(c)(2), such that an issuer offering QHPs in an FFE or SBE-FP, for PY 2025 and subsequent plan years, is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of “product” at § 144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), in any service area.

We propose a similar conforming amendment to § 156.202(d), such that for PY 2025 and subsequent plan years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), and service area if it demonstrates that these additional plans’ cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in an issuer’s other non-standardized plan option offerings in the same product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage, and service area.

We propose these modifications to align the regulation text with the existing flexibility that issuers have been operationally permitted since the non-standardized plan option limit was introduced in the 2024 Payment

Notice.²⁷¹ Given that issuers have had this flexibility since the non-standardized plan option limit was first introduced PY 2024, we do not any anticipate any impact on relevant interested parties.

We seek comment on these impact estimates and assumptions.

18. Essential Community Provider Certification Review for States Performing Plan Management Functions (§ 156.235)

This proposal to conduct ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions beginning in PY 2026 would not have a significant financial impact on the Federal government. HHS continues to perform ECP certification reviews for plans in the FFEs, so the financial burden to conduct the certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions using the existing data infrastructure is a marginal increase within the annual programming for QHP certifications. For PY 2025, HHS would use MPMS for ECP reviews for plans seeking QHP certification in FFEs, and HHS has all the necessary data infrastructure and operational processes to conduct reviews for States performing plan management functions for PY 2026 as proposed. While the Federal government would undertake additional administrative work to review the ECP data from QHP certification applications submitted by issuers seeking certification of their plans as QHPs in FFEs in States performing plan management functions, the transfer of administrative impact from the State that had been performing these reviews to the Federal government is marginal, as the Federal government already has in place processes and procedures to conduct the ECP certification reviews. HHS would continue ECP QHP certification reviews in all other FFE States.

This proposal would reduce the administrative burden for these States as they would no longer be responsible for ECP data review. We estimate a cost savings of \$157,052.70 per State annually for each of the 12 FFE States performing plan management functions in PY 2026.²⁷² This is calculated by

taking the mean hourly wage for a compliance officer of \$38.55, according to the Occupational Employment and Wage Statistics,²⁷³ and adding 100 percent fringe benefits to total \$77.10. We estimate the operations and maintenance costs for the ECP QHP data collection and the QHP data collection support to equal 485 hours for 4.2 full-time equivalents,²⁷⁴ totaling \$157,052.70. The total cost across the 12 FFE States performing plan management functions would be \$1,884,632.40. This cost associated with ECP enforcement/compliance reviews would be transferred from the States performing plan management functions to the Federal government. We further estimate an annual cost of \$8,155 associated with ECP compliance reviews that would be transferred from the FFEs in States performing plan management functions to the Federal government based on current contract costs.

Further, this proposal should not lead to increased burden for issuers in the FFE in States performing plan management functions as they would still have to submit ECP data to HHS regardless of whether it is the State or HHS conducting the QHP certification review. In previous years, these issuers were required to submit ECP data to HHS via the SERFF binders, whereas these issuers are now required to submit their ECP data to HHS in MPMS beginning with the PY 2025 QHP application submission season, making it now possible for HHS to begin reviewing these ECP data going forward.

In addition, this proposal would not financially impact providers on the HHS ECP list.²⁷⁵ There is no fee to be included in the HHS ECP list, and the administrative burden to complete the petition continues to be the same. The proposal would support consumer access to vitally important medical and dental services, enhancing health equity

Hawaii, Iowa, Kansas, Michigan, Montana, Nebraska, New Hampshire, Ohio, South Dakota, Utah, and West Virginia.

²⁷³ Occupational Employment and Wage Statistics from the US Bureau of Labor Statistics for job code 13-1041 Compliance Officer from <https://www.bls.gov/oes/current/oes131041.htm>.

²⁷⁴ We estimated 485 hours for 4.2 full time equivalent similar to the administrative burden cost for the Federal government as indicated in cost estimate of the Supporting Statement for Continuation of Data Collection to Support QHP Certification and other Financial Management and Exchange Operations OMB control number: 0938-1187.

²⁷⁵ A non-exhaustive list of available ECPs that primarily serve low-income and medically underserved populations which can be counted toward an issuer's satisfaction of the ECP standard as part of the issuer's QHP application.

for low-income and medically underserved consumers.

We seek comment on these impact estimates and assumptions.

19. HHS–RADV Materiality Threshold for Rerunning HHS–RADV Results (§ 156.1220(a)(2))

We propose to amend § 156.1220(a)(2) to codify a materiality threshold for when HHS would rerun HHS–RADV results in response to a successful HHS–RADV appeal. We believe that this proposal supports providing stability for issuers that participate in risk adjustment because it limits the potential for issuers to reopen their books for small changes to their State transfers because of a successful HHS–RADV appeal. This proposal would avoid situations where HHS is required to rerun HHS–RADV results, and for all issuers to reopen their books, when the impact for the filer of a successful HHS–RADV appeal is less than \$10,000. Because this approach is limited to small dollar amounts, we do not believe that the proposal would materially impact issuers or their premiums and it would provide stability to issuers by limiting the situations where their books would need to be reopened. We believe that this proposal, when applicable, would reduce Federal costs by an estimated \$75,000 due to the estimated 575 hours of contractor work. We also believe that this proposal, when applicable, would reduce Federal costs through a decrease in HHS staff work hours. These HHS staff are funded by the risk adjustment user fee, therefore there is no cost impact. Rerunning HHS–RADV results requires HHS to recalculate all national metrics, reissue all issuers' error rate results, and then apply all of those revised error rates to State transfers for the applicable benefit year before going through the process to net, invoice, collect, and redistribute the changes to the HHS–RADV adjustments to State transfers.

20. Medical Loss Ratio (§§ 158.103, 158.140, 158.240)

We propose to add a definition of “qualifying issuer” to § 158.103, amend § 158.140(b)(4)(ii) to allow qualifying issuers to not adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes beginning with the 2026 MLR reporting year, amend § 158.240(c) to add an illustrative example of how qualifying issuers would determine the amount of rebate owed to each enrollee, and make a conforming amendment to § 158.240(c) to clarify that the current illustrative example in paragraph (c)(2)

²⁷¹ CMS. (2024, April 10). *2025 Final Letter to Issuers in the Federally-facilitated Exchanges*. <https://www.cms.gov/files/document/2025-letter-issuers.pdf>.

²⁷² Twelve FFEs operate in States performing plan management functions for PY 2026: Delaware,

would apply to issuers that are not qualifying issuers. These proposals, which would extend only to issuers whose ratio of net payments related to the risk adjustment program under section 1343 of the ACA, to earned premiums prior to accounting for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs (as described in § 158.130(b)(5)) in a relevant State and market is greater or equal to 50 percent, would result in transfers to such issuers from their enrollees in the form of lower rebates or higher premiums. Based on MLR data for 2022, these proposals would reduce rebates paid by issuers to consumers or increase premiums collected by issuers from consumers by a total of approximately \$20 million per year.

Under the alternative approach we are considering, in which the proposed amendments to § 158.140(b)(4)(ii) and § 158.240(c) would extend to all issuers subject to the risk adjustment program, based on 2022 MLR data, these proposed amendments would reduce rebates paid by issuers to consumers or increase premiums collected by issuers from consumers by a net total of approximately \$164 million per year.

We seek comment on these impact estimates and assumptions.

21. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that a range of between the total number of unique commenters on last year's proposed rule (251) and the total number of page views on last year's proposed rule (about 10,000) will include the actual number of reviewers of this proposed rule. We therefore use an average number of approximately 5,125 reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some page viewers did not actually read the proposed rule. For these reasons, we believe that the average of the number of commenters and number of page views on last year's proposed rule would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 55 percent of the rule (an average of the range from 10 percent to 100 percent of the rule). We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$106.42 per hour, including overhead and fringe benefits.²⁷⁶ Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 3.6 hours for the staff to review 55 percent of this proposed rule. For each entity that reviews the rule, the estimated cost is \$383.11 (3.6 hours × \$106.42 per hour). Therefore, we estimate that the total cost of reviewing this regulation is approximately \$1,963,438.75 (\$383.11 per reviewer × 5,125 reviewers).

D. Regulatory Alternatives Considered

Under § 153.630(b), we propose to exclude enrollees without HCCs, remove the FPC, and change the source of the Neyman allocation data used to calculate the standard deviation of risk score error from MA-RADV data to HHS-RADV data beginning with the 2025 benefit year of HHS-RADV.

The proposed IVA sampling methodology would use the most recent 3 consecutive years of HHS-RADV data with results that have been released before that benefit year's HHS-RADV activities begin to calculate a national variance of net risk score error to calculate each issuer's standard deviation of risk score error used in the Neyman allocation formula, whereas the current IVA sampling methodology relies on MA-RADV data to calculate this national variance of net risk score error.²⁷⁷ When investigating the impact of switching the Neyman allocation data source to the most recent 3 consecutive years of HHS-RADV data with results that have been released before that benefit year's HHS-RADV activities

begin, we considered creating an issuer-specific variance of net risk score error to calculate each issuer's standard deviation of risk score error used in the Neyman allocation formula. However, it would not be possible to calculate an issuer-specific variance of net risk score error for all issuers participating in a given benefit year of HHS-RADV as some issuers would not have 3 consecutive years of HHS-RADV data. As explained earlier in this preamble, these issuers would have to rely on less years of HHS-RADV data under an issuer-specific calculation, meaning significantly fewer data points compared to other issuers that participated in all years, which could result in large variations in IVA sample stratum size and increased uncertainty in HHS-RADV. Therefore, we propose to continue calculating each issuer's standard deviation of risk score error using a national variance of net risk score error, but to use a 3-year rolling window of HHS-RADV data rather than the MA-RADV data as the source data for the Neyman allocation.

We considered proposing to replace the source of the Neyman allocation data while continuing to include enrollees without HCCs in IVA sampling and retaining the FPC.²⁷⁸ However, this would result in sampling a greater proportion of enrollees without HCCs, who do not have risk scores to adjust when calculating issuers' error rates during HHS-RADV. In addition, keeping the FPC while excluding enrollees without HCCs from IVA sampling and replacing the source data for the Neyman allocation with available HHS-RADV data would lead to a dramatic increase in the number of issuers subject to the FPC and therefore decrease the total count of Super HCCs in issuers' IVA samples. For example, we estimate that the average Super HCC count for issuers currently subject to the FPC would decrease by 26 percent by retaining the FPC, which would increase the proportion of issuers that fail to meet the 30 Super HCC constraint in HHS-RADV.²⁷⁹ In contrast, removing the FPC would increase the average Super HCC count for these same issuers by 30 percent, which would improve issuers' probability of meeting the 30 Super HCC constraint. Overall, our analyses found that making these modifications in combination would lead to the greater improvements in

²⁷⁶ U.S. Bureau of Labor Statistics. (2024, April 9). *Occupational Employment and Wage Statistics*. https://www.bls.gov/oes/current/oes_nat.htm.

²⁷⁷ As noted in the preamble of this rule, a new benefit year of HHS-RADV activities generally begins in the spring when issuers can start selecting their IVA entity and IVA entities can start electing to participate in HHS-RADV for that benefit year. We would use data from the 3 most recent consecutive years of HHS-RADV where results have been released. See, for example, the 2023 Benefit Year HHS-RADV Activities Timeline for the general structure of the HHS-RADV timeline. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.

²⁷⁸ As explained in the preamble of this rule, enrollees without HCCs include stratum 10 enrollees that do not have HCCs nor RXCs and RXC-only enrollees in strata 1 through 3.

²⁷⁹ As noted earlier in this preamble, this estimate is based on the combined impact of all proposed changes to the IVA sampling methodology.

sampling precision and would allow more than 95 percent of issuers to pass the 10 percent sampling precision target at a two-sided 95 percent confidence level.

We also considered only excluding stratum 10 enrollees from the IVA sampling methodology and retaining RXC-only enrollees in strata 1 through 3. However, we believe removing all enrollees without HCCs (both stratum 10 enrollees and RXC-only enrollees) is the preferred approach so issuers and IVA Entities are not spending resources on enrollees who do not have risk scores to adjust when calculating issuers' error rates during HHS–RADV. In addition, our analysis reveals the greatest improvements in precision and greatest decreases in the average medical records reviewed per enrollee, and therefore the greatest decreases in issuer and IVA Entity burden, when excluding RXC-only enrollees and stratum 10 enrollees from the IVA sampling methodology.

As an alternative respect to the SVA pairwise means test proposal we considered only changing the pairwise means testing procedure from the 95 percent confidence interval paired t-test to the 90 percent confidence interval bootstrapped test without increasing the initial SVA subsample size to 24. However, our analysis found that maintaining an initial SVA subsample size of 12 under the bootstrapping methodology did not achieve an optimal target false negative rate of approximately 20 percent at various effect sizes. Therefore, we are proposing to modify the pairwise means test to use a 90 percent confidence interval bootstrapping methodology and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV.²⁸⁰

²⁸⁰ A standard IVA sample size is 200 enrollees, and it applies to the majority of issuers of risk adjustment covered plans. CMS calculates a smaller IVA sample sizes for issuers for smaller populations by using a Finite Population Correction (FPC) factor. All issuers are subject to the same SVA subsample sizes, but the maximum SVA subsample for pairwise testing is one half of the issuer's IVA sample size. As discussed in section II.B.5.a., we are proposing changes to the IVA sampling methodology that would exclude enrollees without HCCs from IVA sampling and remove the FPC factor such that all IVA samples will consist of 200 enrollees with HCCs or the issuer's total EDGE population of enrollees with HCCs if they have less than 200 enrollees with HCCs beginning with the 2025 benefit year of HHS–RADV. Under this policy, the SVA subsample size expansion for issuers with less than 200 enrollees with HCCs would continue to follow the standard SVA subsample sizes with a maximum SVA subsample for pairwise testing equal to one half of the issuer's IVA sample size. If the issuer fails at the maximum SVA subsample size for pairwise testing, a precision analysis is performed to determine whether the SVA audit results from that maximum SVA subsample size can

We considered taking no action regarding the proposed changes at § 155.305(f)(4)(ii) and instead relying on the guidance released by CMS to inform Exchanges of noticing best practices as was previously done, but instead decided to codify this as a requirement to ensure that tax filers or their enrollees receive multiple educational notices regarding the requirement to file their Federal income taxes and reconcile their APTC.

We considered taking no action regarding our proposal to modify § 155.400(g) to allow issuers to adopt a fixed-dollar premium payment threshold or a gross premium-based percentage payment threshold. However, the proposal would provide important flexibility to issuers that wish to allow enrollees who owe de minimis amounts of premium to maintain their enrollment. This flexibility is limited under current regulation, and as a result enrollees who owe small amounts of premium are sometimes unable to remain enrolled. We are soliciting feedback from interested parties on whether a fixed-dollar threshold, or a percentage threshold based on gross premium, would better meet our goal of providing flexibility to issuers to allow enrollees to avoid triggering a grace period and termination of enrollment through the Exchange for owing small amounts of premium. For the fixed-dollar premium payment threshold, we are also considering whether to implement a \$5 or \$10 cap on the fixed-dollar threshold because while we believe the \$5 cap is sufficient to help many enrollees avoid termination, CMS data on non-payment terminations also indicate that there are a considerable number of policies that were terminated in PY2023 with a member responsibility amount of \$10 or less. We are soliciting feedback from interested parties in order to determine what the appropriate cap should be on the fixed-dollar threshold. We also considered keeping the existing net premium-based threshold at a “reasonable” limit, which we recommended to be 95 percent or higher, but are proposing to specifically define the threshold at 95 percent or higher, in order to provide clarity for issuers and Exchanges. We also considered whether it would be administratively feasible to allow issuers to adopt both a fixed-dollar and percentage-based threshold but restricted issuers to choosing one threshold method. We are soliciting feedback from interested parties on

be used in error estimation or if the SVA sample needs to expand to the full IVA sample.

whether we should allow this flexibility.

For the proposed 2026 benefit year FFE and SBE–FP user fees, we considered only proposing one FFE user fee rate and one SBE–FP user fee rate as we have done in previous years. However, we recognize that the expiration of the enhanced PTC subsidies at the end of the 2025 benefit year creates a significant amount of uncertainty in the ACA markets and despite this uncertainty, we maintain our interest in ensuring that we collect user fees at a rate that will allow us to sustain the operations of the FFEs. Therefore, we are proposing an FFE user fee rate of 2.5 percent of monthly premiums for the 2026 benefit year, which is greater than the FFE user fee rate finalized in the 2025 Payment Notice (89 FR 26336 through 26338) of 1.5 percent of total monthly premiums, and if the enhanced PTC subsidies as currently enacted or at a higher level are extended through the 2026 benefit year by March 31, 2025, we are also proposing a 2026 benefit year FFE user fee rate range between 1.8 and 2.2 percent of total monthly premiums and a 2026 benefit year SBE–FP user fee rate range between 1.4 and 1.8 of total monthly premiums, with each of these ranges to be set at a single rate in the final rule.

We considered taking no action regarding our proposal to conduct ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions under § 156.235. Not conducting reviews as proposed would maintain current certification operations for issuers in FFE States that perform plan management functions and continue to provide States with the ability to use a similar approach to Federal ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs. However, due to the implementation of the MPMS and enhancement of the ECP user interface, issuers seeking QHP certification in FFEs, including States performing plan management functions, can now submit ECP data to HHS for data integrity of the Federal platform regardless of whether it is the State or HHS conducting the review.

We propose to amend § 156.1220(a)(2) to codify when HHS would take action in response to a successful HHS–RADV appeal. We considered several ways to design the new materiality threshold to rerun HHS–RADV results. For example, we considered setting the second materiality threshold to rerun HHS–RADV results to include a percentage of

HHS–RADV adjustments and applying a 1 percent test to align with the EDGE materiality threshold in § 153.710(e). However, considering that the HHS–RADV adjustments to State risk adjustment transfer charges and State risk adjustment transfer payments are orders of magnitude smaller than those of the initial State risk adjustment transfer amounts, we were concerned that we would see situations where 1 percent of the applicable payment or charge could be as little as \$10 based on our experience running HHS–RADV for the past few years. Specifically, we believe that structuring the threshold, as proposed, to the financial impact of the filer and applying an equal to or greater than \$10,000 amount would balance the need for ensuring that HHS–RADV results are accurate with the desire for ensuring that changes in HHS–RADV results actually have a meaningful financial impact. This proposed new materiality threshold to rerun HHS–RADV results takes into consideration the existing materiality threshold for filing a request for reconsideration, which applies to a number of different program appeals. To remain consistent with this existing threshold and recognizing that HHS–RADV adjustments are significantly smaller in magnitude than risk adjustment transfers, we believe that \$10,000 is a reasonable threshold, but we solicit comment on this dollar amount and whether it should be higher or lower or whether we should consider including an inflation adjustment rate to this amount. This new proposed materiality threshold to rerun HHS–RADV results also considers the fact that it costs HHS approximately \$75,000 to rerun HHS–RADV and re-release results. Reducing the number of times HHS–RADV needs to be rerun and HHS–RADV adjustments need to be re-released also helps maintain the stability of the market, as there are fewer instances of adjustments after the initial release of HHS–RADV adjustments.

E. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that small businesses, nonprofit organizations, and small governmental jurisdictions are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than \$8.0 million to \$41.5 million in any 1 year). We do not anticipate that providers would be directly impacted by the proposals in this proposed rule. Individuals and States are not included in the definition of a small entity. The proposals in this proposed rule would affect Exchanges and QHP issuers.

For purposes of the RFA, we believe that health insurance issuers would be classified under the NAICS code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$47 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 will be \$44.5 million or less.²⁸¹ We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) would fall below these size thresholds. Based on data from MLR annual report submissions for the 2022 MLR reporting year, approximately 87 out of 487 issuers of health insurance coverage nationwide had total premium revenue of \$47 million or less.²⁸² This estimate may overstate the actual number of small health insurance issuers that may be affected, since over 76 percent of these small issuers belong to larger holding

groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding \$47 million. Therefore, although it is likely that fewer than 87 issuers are considered small entities, for the purposes of this analysis, we assume 87 small issuers would be impacted by this proposed rule.

The proposed policies that would result in an increased burden to small entities are described below.

We propose to update the IVA sampling methodology, including the proposed removal of enrollees without HCCs (including RXC-only enrollees), removing the FPC, and replacing the source of the Neyman allocation data with the most recent 3 years of consecutive HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin, beginning with benefit year 2025 HHS–RADV. The total cost savings associated with this proposal would be approximately \$79,121.92 per issuer audited per year. For more details, please refer to the Regulatory Impact Analysis section associated with this policy in this proposed rule.

We propose to add a definition of “qualifying issuer” and to no longer require such issuers to adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes. This proposal would reduce rebates paid by these issuers to consumers or increase premiums collected by these issuers from consumers by approximately \$20 million annually. The cost savings per issuer would therefore be approximately \$41,067.76.²⁸³ For more details, please refer to the Regulatory Impact Analysis section associated with this policy in this proposed rule.

Thus, the per-entity estimated annual cost savings for small issuers is \$120,189.68, and the total estimated annual cost savings for small issuers is \$10,456,502.16. See tables 18 and 19.

TABLE 18: Detailed Annual Costs for Small Entities

Description of Cost	Annual Cost per Small Entity
HHS–RADV IVA changes	-\$79,121.92
MLR changes	-\$41,067.76
Total	-\$120,189.68

²⁸¹ SBA. (n.d.). *Table of size standards*. <https://www.sba.gov/document/support-table-size-standards>.

²⁸² CMS. (n.d.). *Medical Loss Ratio Data and System Resources*. <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

²⁸³ \$20 million/487 issuers participating in the MLR program = approximately \$41,076.67.

TABLE 19: Aggregate Annual Costs for Small Entities

Affected Entity	Affected Small Entities	Annual Cost per Entity	Aggregate Annual Cost for Small Entities
Issuer	87	-\$120,189.68	-\$10,456,502.16

We seek comment on this analysis and seek information on the number of small issuers that may be affected by the provisions in these proposed rules.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule, given that the annual per-entity cost savings of \$120,189.68 per small issuer represents approximately 0.06 percent of the average annual receipts for a small issuer.²⁸⁴ Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For the 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 rule will not affect small rural hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately \$183 million. Although we have not been able to quantify all costs, we expect that the combined impact on State, local, or

Tribal governments and the private sector does not meet the UMRA definition of unfunded mandate.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, we have engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the NAIC, and consulting with State insurance officials on an individual basis.

While developing this rule, we attempted to balance the States' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, we complied with the requirements of Executive Order 13132.

Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For States that elected previously to operate an Exchange, those States had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In our view, while this proposed 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 proposal to conduct ECP certification reviews for States performing plan management functions effective beginning in plan year 2026 may have Federalism implications, given that HHS has not conducted Federal ECP certification reviews for States performing plan management functions since the 2015 plan year. However, these Federalism implications may be balanced by enabling HHS to align standards in these States with Federal review standards, and thereby increasing consumer access in these States and improving efficiency of the QHP certification process. Additionally, we do not believe that the proposed amendment to codify the timeliness guidance for State Exchanges to review and resolve the State Exchange issuers enrollment data inaccuracies within 60 calendar days would have significant Federalism implications because this proposal is merely codifying a timeline for an existing data submission requirement.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 30, 2024.

List of Subjects

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs—health, Grants

²⁸⁴ United States Census Bureau (2020, March). 2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size. <https://www.census.gov/data/tables/2020/econ/susb/2020-susb-annual.html>.

administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

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 proposes to amend 45 CFR subtitle A, subchapter B, as set forth below.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 1. 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.

■ 2. Section 155.220 is amended by revising paragraph (k)(3) to read as follows:

§ 155.220 Ability of States to permit agents, brokers, web-brokers, and agencies to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(k) * * *

(3) HHS may immediately suspend the agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under paragraph (j)(2)(i), (ii), or (iii) of this section and the privacy and security standards under § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction.

* * * * *

■ 3. Section 155.305 is amended by adding paragraph (f)(4)(ii) to read as follows:

§ 155.305 Eligibility standards.

* * * * *

(f) * * *

(4) * * *

(ii) If HHS notifies the Exchange as part of the process described in § 155.320(c)(3) that APTC payments were made on behalf of either the tax filer or their spouse, if the tax filer is a married couple, for 2 consecutive tax years for which tax data would be utilized for verification of household income and family size in accordance with § 155.320(c)(1)(i), and the tax filer or the tax filer's spouse did not comply with the requirement to file an income tax return for both years as required by 26 U.S.C. 6011, 6012, and their implementing regulations and reconcile APTC for that period ("file and reconcile"), the Exchange must:

(A) Send a direct notification to the tax filer, consistent with the standards applicable to the protection of Federal Tax Information, that explicitly informs the tax filer that the Exchange has determined that the tax filer or the tax filer's spouse, if the tax filer is married, has failed to file their Federal income taxes and reconcile APTC, and educate the tax filer of the need to file and reconcile or risk being determined ineligible for APTC after 2 consecutive years of failing to file and reconcile; or

(B) Send an indirect notification to either the tax filer or their enrollee, that informs the tax filer or enrollee that they may be at risk of being determined ineligible for APTC after 2 years of failing to file and reconcile. These notices must educate tax filers or their enrollees on the requirement to file and reconcile, while not directly stating that the Internal Revenue Service indicates the tax filer or the tax filer's spouse, if the tax filer is married, has failed to file and reconcile.

* * * * *

■ 4. Section 155.400 is amended by adding paragraph (d)(1) and a reserved paragraph (d)(2) and revising paragraph (g) to read as follows:

§ 155.400 Enrollment of qualified individuals into QHPs.

* * * * *

(d) * * *

(1) *Timeliness standard for State Exchanges to review, resolve, and report data inaccuracies submitted by a State Exchange issuer.* Within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in the State Exchange that includes a description of a data inaccuracy in accordance with § 156.1210 and all the information that the State Exchange requires or requests to properly assess the inaccuracy, the State Exchange must

review and resolve the State Exchange issuer's data inaccuracies and submit to HHS a description of the resolution of the inaccuracies in a format and manner specified by HHS.

(2) [Reserved]

* * * * *

(g) *Premium payment threshold.*

Exchanges may, and the Federally-facilitated Exchanges and State-Based Exchanges on the Federal platform will, allow issuers to implement either a percentage-based premium payment threshold policy (which can be based on either the net premium after application of advance payments of the premium tax credit or gross premium) or a fixed-dollar premium payment threshold policy, provided that the threshold and policy is applied in a uniform manner to all applicants and enrollees.

(1) Under a net premium percentage-based premium payment threshold policy, issuers can consider applicants or enrollees to have paid all amounts due for the following purposes, if the applicants or enrollees pay an amount sufficient to maintain a percentage of total premium paid out of the total premium owed equal to or greater than 95 percent of the net monthly premium amount owed by the enrollees. If an applicant or enrollee satisfies the percentage-based premium payment threshold policy, the issuer may:

(i) Effectuate an enrollment based on payment of the binder payment under paragraph (e) of this section.

(ii) Avoid triggering a grace period for non-payment of premium, as described by § 156.270(d) of this subchapter or a grace period governed by State rules.

(iii) Avoid terminating the enrollment for non-payment of premium as, described by §§ 156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and (B).

(2) Under a gross premium percentage-based premium payment threshold policy, issuers can consider enrollees to have paid all amounts due for the following purposes, if the enrollees pay an amount sufficient to maintain a percentage of the gross premium of the policy before the application of advance payments of the premium tax credit that is equal to or greater than 99 percent of the gross monthly premium owed by the enrollees. If an enrollee satisfies the gross premium percentage-based premium payment threshold policy, the issuer may:

(i) Avoid triggering a grace period for non-payment of premium, as described by § 156.270(d) of this subchapter or a grace period governed by State rules.

(ii) Avoid terminating the enrollment for non-payment of premium as,

described by §§ 156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and (B).

(3) Under a fixed-dollar premium payment threshold policy, issuers can consider enrollees to have paid all amounts due for the following purposes, if the enrollees pay an amount that is less than the total premium owed, the unpaid remainder of which is equal to or less than a fixed-dollar amount of \$5 or less, adjusted for inflation, as prescribed by the issuer. If an enrollee satisfies the fixed-dollar premium payment threshold policy, the issuer may:

(i) Avoid triggering a grace period for non-payment of premium, as described by § 156.270(d) of this subchapter or a grace period governed by State rules.

(ii) Avoid terminating the enrollment for non-payment of premium as, described by §§ 156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and (B).

* * * * *

■ 5. Section 155.505 is amended by revising paragraph (b) introductory text to read as follows:

§ 155.505 General Eligibility Appeals Requirements.

* * * * *

(b) *Right to appeal.* An applicant, enrollee, or application filer must have the right to appeal.

* * * * *

■ 6. Section 155.1000 is amended by adding paragraph (e) to read as follows:

§ 155.1000 Certification standards for QHPs.

* * * * *

(e) *Denial of certification.* The Exchange may deny certification to any plan that does not meet the general certification criteria under § 155.1000(c).

■ 7. Section 155.1090 is amended by revising the section heading, the paragraph (a) heading, and paragraphs (a)(2) and (3) to read as follows:

§ 155.1090 Request for the reconsideration of a denial of certification.

(a) *Request for the reconsideration of a denial of certification specific to a Federally-facilitated Exchange—*

* * * * *

(2) *Form and manner of request.* An issuer submitting a request for reconsideration under paragraph (a)(1) of this section must submit a written request for reconsideration to HHS, in the form and manner specified by HHS, within 7 calendar days of the date of the written notice of denial of certification. The issuer must include any and all documentation the issuer wishes to

provide in support of its request with its request for reconsideration. The request for reconsideration must provide clear and convincing evidence that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error.

(3) *HHS reconsideration decision.* HHS will review the reconsideration request to determine whether the issuer's reconsideration request provided clear and convincing evidence that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error. HHS will provide the issuer with a written notice of the reconsideration decision. The decision will constitute HHS' final determination.

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 8. The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 9. Section 156.201 is amended by adding paragraph (c) to read as follows:

§ 156.201 Standardized plan options.

* * * * *

(c) For PY 2026 and subsequent plan years, an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area must meaningfully differentiate these plans from one another in terms of included benefits, provider networks, and/or formularies. For the purposes of this standard, a standardized plan option with a different product, provider network, and/or formulary ID would be considered meaningfully different.

■ 10. Section 156.202 is amended by revising paragraph (b) and paragraph (d) introductory text to read as follows:

§ 156.202 Non-standardized plan option limits.

* * * * *

(b) For plan year 2025 and subsequent plan years, is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of “product” at § 144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1)

through (3) of this section), in any service area.

* * * * *

(d) For plan year 2025 and subsequent plan years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of this section), and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in the issuer's other non-standardized plan option offerings in the same product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage, and service area.

* * * * *

■ 11. Section 156.1220 is amended by adding paragraph (a)(2)(i) and reserved paragraph (a)(2)(ii) to read as follows:

§ 156.1220 Administrative appeals.

(a) * * *

(2) * * *

(i) Notwithstanding paragraph (a)(1) and (2) of this section, for appeals related to HHS–RADV under paragraphs (a)(1)(vii) and (viii) of this section, HHS will only take action to adjust risk adjustment State payments and charges for an issuer in response to an appeal decision when the impact of the decision to the filer's HHS–RADV adjustments to risk adjustment State transfers is greater than or equal to \$10,000.

(ii) [Reserved]

* * * * *

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 12. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg–18.

■ 13. Section 158.103 is amended by adding a definition for “Qualifying issuer” in alphabetical order to read as follows:

§ 158.103 Definitions.

* * * * *

Qualifying issuer means an issuer whose ratio of net payments related to

the risk adjustment program under section 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18063, to earned premiums prior to accounting for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs (as described in § 158.130(b)(5)) in a relevant State and market is greater than or equal to 50 percent.

* * * * *

■ 14. Section 158.140 is amended by revising paragraph (b)(4)(ii) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(4) * * *

(ii) Beginning with the 2026 MLR reporting year, for qualifying issuers (as defined in § 158.103), receipts related to the transitional reinsurance program and net payments or receipts related to the risk corridors program (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent) under sections 1341 and 1342 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062. For all other issuers, receipts related to the transitional reinsurance program and net payments or receipts related to the risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent) under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

* * * * *

■ 15. Section 158.240 is amended by revising paragraph (c)(2) and adding paragraph (c)(3) to read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(c) * * *

(2) For example, an issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR

for the individual market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the individual market in a State that has not set a higher MLR, the issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting a pro rata portion of taxes and fees and accounting for payments or receipts related to the reinsurance, risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent). If the issuer is not a qualifying issuer (defined in § 158.103), the issuer's total earned premium for the MLR reporting year in the individual market in the State is \$200,000, incurred claims are \$121,250, the issuer received transitional reinsurance payments of \$2,500, and made net payments related to risk adjustment and risk corridors of \$20,000 (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent), then the issuer's gross earned premium in the individual market in the State would be \$200,000 plus \$2,500 minus \$20,000, for a total of \$182,500. If the issuer's Federal and State taxes and licensing and regulatory fees, including reinsurance contributions, that may be excluded from premium revenue as described in §§ 158.161(a), 158.162(a)(1), and 158.162(b)(1), allocated to the individual market in the State are \$15,000, and the net payments related to risk adjustment and risk corridors, reduced by reinsurance receipts, that must be accounted for in premium revenue as described in §§ 158.130(b)(5), 158.221, and 158.240, are \$17,500 (\$20,000 reduced by \$2,500), then the issuer would subtract \$15,000 and add \$17,500 to gross premium revenue of \$182,500, for a base of \$185,000 in adjusted premium. The issuer would owe rebates of 5 percent of \$185,000, or \$9,250 in the individual market in the State. In this example, if an enrollee of the issuer in the individual market in the State paid \$2,000 in premiums for the MLR

reporting year, or 1/100 of the issuer's total premium in that State market, then the enrollee would be entitled to 1/100 of the total rebates owed by the issuer, or \$92.50.

(3) As another example, if an issuer is a qualifying issuer (defined in § 158.103), the issuer's total earned premium for the MLR reporting year in the individual market in the State is \$90,000, incurred claims are \$151,250, and the issuer received transitional reinsurance payments of \$12,500 and net receipts related to risk adjustment of \$110,000, then the issuer's gross earned premium in the individual market in the State would be \$90,000 plus \$12,500, for a total of \$102,500. If the qualifying issuer's Federal and State taxes and licensing and regulatory fees, including reinsurance contributions, that may be excluded from premium revenue as described in §§ 158.161(a), 158.162(a)(1), and 158.162(b)(1), allocated to the individual market in the State are \$15,000, and the reinsurance payments that must be accounted for in premium revenue as described in §§ 158.130(b)(5), 158.221, and 158.240 are \$12,500, then the qualifying issuer would subtract \$15,000 and \$12,500 from gross premium revenue of \$102,500, for a subtotal of \$75,000. The qualifying issuer would then add \$110,000 in net receipts related to risk adjustment, for a base of \$185,000 in adjusted premium. The qualifying issuer would owe rebates of 5 percent of \$185,000, or \$9,250 in the individual market in the State. In this example, if an enrollee of the issuer in the individual market in the State paid \$900 in premiums for the MLR reporting year, or 1/100 of the issuer's total premium in that State market, then the enrollee would be entitled to 1/100 of the total rebates owed by the issuer, or \$92.50.

* * * * *

Dated: October 2, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–23103 Filed 10–4–24; 4:15 pm]

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Part III

Environmental Protection Agency

40 CFR Part 82

Protection of Stratospheric Ozone: Updates Related to the Use of Ozone-Depleting Substances as Process Agents; Final Rule

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 82****[EPA-HQ-OAR-2022-0707; FRL-9603-02-OAR]****RIN 2060-AV65****Protection of Stratospheric Ozone: Updates Related to the Use of Ozone-Depleting Substances as Process Agents****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This action establishes recordkeeping and reporting requirements for uses of ozone-depleting substances as process agents and updates related definitions. Codified recordkeeping and reporting requirements will provide clear notice of information the U.S. Environmental Protection Agency collects, aggregates, and reports each year on behalf of the United States as a party to the Montreal Protocol on Substances that Deplete the Ozone Layer; effectively monitor these narrow uses in a more routine and consistent manner under the Clean Air Act; and enhance understanding of emissions of substances harmful to the stratospheric ozone layer.

DATES: This final rule is effective on November 12, 2024. The incorporation by reference (IBR) of certain publications listed in the rule is approved by the Director of the Federal Register as of November 12, 2024.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA-HQ-OAR-2022-0707. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information may not be publicly available, *e.g.*, confidential 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>.

FOR FURTHER INFORMATION CONTACT: John Feather, Stratospheric Protection Division, Office of Atmospheric Protection (Mail Code 6205A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202-564-1230; or email address: feather.john@epa.gov. You may also visit EPA's

website at <https://www.epa.gov/ozone-layer-protection> for further information.

SUPPLEMENTARY INFORMATION:

Throughout this document, whenever “we,” “us,” “the Agency,” or “our” is used, we mean the EPA. Acronyms that are used in this rulemaking that may be helpful include:

ASME—American Society of Mechanical Engineers
CAA—Clean Air Act
CEMS—continuous emissions monitoring system
CFC—chlorofluorocarbon
CFR—Code of Federal Regulations
CRA—Congressional Review Act
EPA—U.S. Environmental Protection Agency
FOIA—Freedom of Information Act
FTIR—Fourier-transform infrared spectroscopy
GHGRP—Greenhouse Gas Reporting Program
HCFC—hydrochlorofluorocarbon
HFC—hydrofluorocarbon
IBR—incorporation by reference
ICR—Information Collection Request
NAICS—North American Industry Classification System
NARA—National Archives and Records Administration
ODP—ozone depletion potential
ODS—ozone-depleting substances
PRA—Paperwork Reduction Act
RFA—Regulatory Flexibility Act
SISNOSE—Significant Economic Impact on a Substantial Number of Small Entities
TEAP—Technology and Economic Assessment Panel
TRI—Toxics Release Inventory
UMRA—Unfunded Mandates Reform Act

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- J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All
- K. Congressional Review Act (CRA)

I. General Information**A. Does this action apply to me?**

You may be potentially affected by this action if you use ozone-depleting substances¹ (ODS) as process agents. Potentially affected categories, North American Industry Classification System (NAICS) codes, and examples of potentially affected entities include Industrial Gas Manufacturing (NAICS code 325120), Other Basic Inorganic Chemical Manufacturing (NAICS code 325180), and All Other Basic Organic Chemical Manufacturing (NAICS code 325199).

This list is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this section could also be affected. If you have any questions regarding the applicability of this action to a particular entity,² consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What action is the Agency taking?

This action is narrow in scope and primarily codifies reporting and recordkeeping requirements for a limited number of chemical manufacturing facilities. EPA annually

¹ For the purposes of this preamble, EPA uses “ozone-depleting substance” and “controlled substance” interchangeably. Both terms are intended to have the same meaning as “controlled substance” as defined in 40 CFR 82.3.

² In certain instances EPA may use the terms “entity,” “person,” and “company” interchangeably. Because EPA anticipates that the parties that use process agents are companies or other entities, the Agency uses these terms to refer to regulated parties in the rule. Using this shorthand, however, does not alter the applicability of the Clean Air Act (CAA)'s or regulation's requirements and prohibitions. Similarly, in certain instances EPA may use these terms interchangeably in this rule preamble, but such differences in terminology should not be viewed to carry a material distinction in how EPA interprets or is planning to apply the requirements discussed herein.

collects process agent consumption and emissions information. In this action, the Agency is codifying reporting requirements to collect this information, including a methodology to calculate emissions. EPA is also defining the term “process agent,” revising definitions of “plant” and “facility” to better reflect current practice, and establishing definitions associated with the emission reporting requirements.

C. What is EPA’s authority for this action?

Several sections of the CAA provide authority for this action. In particular, section 603 provides authority to establish monitoring and reporting requirements for controlled substances. EPA also relies on its authority under section 114 of the CAA, which authorizes the EPA Administrator to establish recordkeeping and reporting requirements in carrying out any provision of the CAA (with certain exceptions that do not apply here). Sections 604 and 605 of the CAA provide the authority to phase out the production and consumption of class I and class II controlled substances, to restrict the use of class I and class II controlled substances, and to promulgate regulations associated with the production of class I and class II controlled substances. EPA’s regulations implementing the production and consumption controls for class I and class II controlled substances, including provisions implementing exceptions to those controls, can be found at 40 CFR part 82, subpart A. Additional authority for electronic reporting, as required under provisions in 40 CFR 82.13(c) and 82.24(a)(1) comes from the Government Paperwork Elimination Act (44 U.S.C. 3504), which provides “(1) for the option of the electronic maintenance, submission, or disclosure of information, when practicable as a substitute for paper; and (2) for the use and acceptance of electronic signatures, when practicable.”

II. Background

A. EPA’s Phaseout of ODS

In 1987, the United States joined 23 other countries and the European Union to sign the *Montreal Protocol on Substances that Deplete the Ozone Layer* (Montreal Protocol) and the United States ratified the Montreal Protocol on April 21, 1988. This international treaty protects and restores the stratospheric ozone layer by phasing out the production and consumption of certain ODS including chlorofluorocarbons (CFCs), halons, methyl bromide, and

hydrochlorofluorocarbons (HCFCs). The Montreal Protocol and its parent treaty, the *Vienna Convention for the Protection of the Ozone Layer*, are the first international treaties to achieve the distinction of having been joined by all countries of the United Nations. The Clean Air Act Amendments of 1990 added title VI on Stratospheric Ozone Protection. Under the CAA and EPA’s regulations at 40 CFR part 82, controls are in place that restrict the production and consumption of ODS to implement the phaseout of these substances. Title VI establishes two classes of controlled ODS: class I and class II controlled substances. Class I controlled substances, *i.e.*, CFCs, halons, carbon tetrachloride, methyl chloroform, methyl bromide, and hydrobromofluorocarbons, have higher ozone depletion potentials (ODPs) and were phased out ahead of class II controlled substances. Class II controlled substances consist only of HCFCs—which have lower ODPs than class I controlled substances—and in many cases acted as transitional substitutes for many class I controlled substances. While existing regulations allow for limited production and consumption of two HCFCs (HCFC-123 and HCFC-124) until 2030, all others have been phased out in the United States. For both class I and class II controlled substances, there are limited exceptions, such as the exclusion from the definition of “production” in 40 CFR 84.3 for controlled substances that are either manufactured and subsequently transformed, *i.e.*, for feedstock uses,³ or destroyed by approved destruction technologies.⁴

B. ODS Used as Process Agents

Process agents are generally understood to be used to create an environment for another process to occur, without themselves being transformed or destroyed during that process. The process agent is not consumed in the reaction, though trace quantities of the process agent may remain in the final product. Certain quantities may also be emitted. For the purposes of this rulemaking, EPA uses the terms “controlled substance used as a process agent”, “ODS process agent”, and “process agent” interchangeably. The Agency also uses the term “consumed” in this context to mean “used up” or transformed.

After initial use, process agents may be reused (with or without recycling),

³ EPA considers terms related to “transformation” and “feedstock uses” to be interchangeable for the purposes of this preamble.

⁴ Approved destruction technologies are listed at 40 CFR 82.3 “Destruction.”

used in transformation reactions, or destroyed. While process agents are generally reused, additional process agents may need to be introduced to replenish losses due to transformation, destruction, emission, or being present in trace quantities in the chemical substance being manufactured. Emissions can be reduced through limiting process agent losses (*e.g.*, mitigate fugitive emissions or capture process agents for further use or destruction) and by directly abating process agent emissions. Technology resulting in zero-emission uses of process agents have increasingly been adopted over time.⁵

C. EPA’s Treatment of ODS Process Agents

Some legacy uses of ODS as process agents continue, in particular where substitutes or alternative processes may not be currently viable, and the Agency annually requests, collects, and reviews information on these uses. This is in line with decisions under the Montreal Protocol to allow the continued use of ODS as process agents under specified situations. The parties to the Montreal Protocol agreed in decision X/14 to except quantities of ODS produced or imported for use as process agents from the general requirements to phase out production and consumption of controlled ODS.⁶ EPA annually prepares information derived from submissions to the Agency on process agent uses in the United States and submits this information to the Montreal Protocol’s Ozone Secretariat on behalf of the United States, consistent with decisions taken by the parties to the Montreal Protocol. On October 19, 2023, EPA proposed to establish recordkeeping and reporting requirements for uses of ODS as process agents and to update definitions to reflect current practice (88 FR 72027). These codified requirements were proposed to monitor process agent uses in a more routine and consistent manner under the Clean Air Act; and enhance understanding of emissions of substances harmful to the stratospheric ozone layer.

III. Reporting and Recordkeeping Requirements

EPA is establishing one-time, annual, and situational reporting for entities that use ODS as process agents, a

⁵ United Nations Environment Programme, Medical and Chemicals Technical Options Committee, 2022 Assessment Report. <https://ozone.unep.org/system/files/documents/MCTOC-Assessment-Report-2022.pdf>.

⁶ <https://ozone.unep.org/treaties/montreal-protocol/meetings/tenth-meeting-parties/decisions/decision-x14-process-agents>.

methodology to estimate emissions, and associated recordkeeping requirements. These requirements will improve the Agency's understanding of process agent uses, efforts to monitor changes that occur over time, and anticipate future changes. Codified recordkeeping and reporting requirements will provide clear and consistent notice of the information EPA will collect each year in order to report consistent with decisions taken by the parties to the Montreal Protocol. These requirements will also further clarify how companies treat and report ODS process agent uses. The Agency is establishing these reporting and recordkeeping requirements for both class I and class II controlled substances that may be used as process agents. These requirements apply to all controlled substances used as process agents, regardless of whether the process agent uses are listed in decisions under the Montreal Protocol.⁷ These reports must be submitted electronically through the Central Data Exchange or another format specified by EPA.

EPA understands that uses in the United States of ODS as process agents are primarily in legacy processes at existing facilities. Based on the information reported and reviewed by the Ozone Secretariat, as well as the discussions held at Montreal Protocol meetings, the United States is one of a few countries that continue to use controlled substances as process agents. The additional recordkeeping and reporting requirements established in this action will support EPA's efforts to assess use of controlled substances as process agents, prepare and report associated information supporting continued need for excepted uses where appropriate, and ensure there is clarity and consistency in reporting on emissions of ODS used as process agents.

This reporting will allow EPA to effectively monitor these narrow process agent uses in a more routine and consistent manner under CAA section 603, and ensure the Agency is accurately documenting production and consumption of class I and class II controlled substances consistent with the limits established under CAA sections 604 and 605.

A. One-Time Report

To establish a baseline set of information from which EPA can monitor potential changes over time,

EPA is generally finalizing as proposed the one-time reporting requirements, with the additional reported data element of the percentage of process agent consumed in the process agent application. The Agency proposed that any facility that uses a controlled substance as a process agent must submit a one-time report. This report must be submitted within 120 days of October 10, 2024, or within 120 days of the date that a facility first uses a controlled substance as a process agent, whichever is later, and is required regardless of whether an entity has provided this information to EPA previously.

EPA proposed that this one-time report include information concerning the controlled substance being used as a process agent; a mass balance describing where, how, and how much of the controlled substance is used and emitted; if relevant, where, how, and how much of the controlled substance is transformed, destroyed, or otherwise captured; data on how much controlled substance was used in the last year and what it was used to produce (e.g., another chemical or product); air emissions from stack point sources, fugitive sources, and total air emissions; actions taken or under evaluation to phase out use of ODS as a process agent (e.g., by transitioning to a non-ozone depleting alternative); actions taken or under evaluation to minimize process agent use or emissions; and the location of the facility using the process agent.

One commenter requested that EPA remove from the reporting requirements the data elements relating to the percentages of class I controlled substances used as a process agent and retained within the process agent application, recovered after the process agent application, and emitted or entrained in the final product. The commenter stated that this baseline information on process agent use is unnecessary because the information would already be provided in the use, volume, and emission data in the annual reports. The commenter further stated that it produces controlled substances for other uses in addition to use as a process agent, and that reporting this baseline information would require a facility to include information associated with all controlled substance production. The commenter stated that process agent use could be a small percentage of overall production, market conditions that drive overall production do not provide a reliable baseline, and reporting on overall production could compromise confidential information associated with manufacturing processes. Alternatively,

the commenter requested that EPA consider this reporting to be confidential and that process knowledge be allowed to serve as the basis for the information requested.

In response, EPA does not agree that reporting elements concerning the percentages of process agent used are unnecessary and would disclose confidential information. Details of the percentages of process agents used will provide EPA information on how other reported information relate to typical chemical manufacturing pathways and may be relevant to future Agency considerations. It is not evident how EPA may identify these values from the aggregated quantities of use, volume, and emission data that entities will report. Considering the variety of internal processes, process cycles, and potential pathways, it is not feasible for EPA to reliably derive the information the Agency is seeking from the data otherwise provided in annual reports. EPA is also not requiring that facilities include in their annual reporting the amounts retained within the process or entrained in the product. The Agency is requiring that this information be included in the one-time reporting to ensure that this process information may be understood within the context of other reported data. Furthermore, these data elements provide useful information that will help address a recommendation from another commenter, discussed in section V of this preamble, concerning what quantities typically remain in a final product. As also discussed in section V of this preamble, EPA is further adding a requirement that the percentage of process agent consumed in the process agent application be included in this one-time report. Information on these data elements from the one-time reports will be relevant to Agency considerations of what may be appropriate thresholds for determining if a use meets the definition of "process agent" codified in this action at 40 CFR 82.3. EPA further understands that the commenter misunderstood this information as being intended to apply across overall production of the given controlled substances instead of the proportion used as process agents. The relevant data elements were, of the amount of controlled substance used as a process agent, what percentages were respectively retained, recovered, emitted, or entrained. These representative percentages of process agent use through a cycle of the process agent application are not relevant to the commenter's concerns that reporting on the overall production may not provide

⁷ EPA encourages entities to contact the Agency for an applicability determination if it is unclear whether a given use of a controlled substance meets EPA's criteria of a process agent use.

a reliable baseline for this one-time report. EPA clarifies that the reported information is intended to represent a typical cycle through a process agent application and entities may, to the best of their ability, apply process knowledge to obtain this information. EPA addresses comments concerning the confidentiality determinations in section IV.B of this preamble.

B. Annual Report

As part of a continuing effort to monitor potential changes over time, EPA is generally finalizing as proposed the requirement that any facility that uses a controlled substance as a process agent must submit an annual report each year by February 14, with the addition of a process for entities to request extensions of reporting due dates. If there are facilities that employ more than one process agent use, any such facilities will need to report data individually for each process that uses an ODS process agent. This information will help enable the Agency to develop annual reports regarding uses of process agents in the United States and to effectively monitor production and consumption of ODS used for process agents consistent with domestic requirements.

EPA proposed to require that each entity with a facility that uses a controlled substance as a process agent must submit for each applicable facility an annual report by February 14 of each year concerning process agent uses for the previous calendar year (*i.e.*, January 1 through December 31). This date coincides with the fourth quarter and certain annual deadlines for related existing ODS reporting requirements, including all quarterly importer and producer reports and the annual reports under 40 CFR 82.13(m) for second party transformation and destruction of class I controlled substances. EPA proposed that these annual reports include information concerning process agent sourcing; amounts recycled, reused, transformed, and destroyed over the previous calendar year; air emissions from stack point sources, fugitive sources, and total air emissions; and a description of emission reduction actions currently in use, planned, or currently under evaluation since the last one-time or annual report.

One commenter supported the proposed reporting on process agent sourcing and on actions taken or under evaluation to phase out use of ODS as a process agent, stating that this information will allow EPA to assess the progress of developing alternatives and possibly end the need for the U.S. exemption for ODS process agents. EPA

acknowledges the commenter's support for the proposed reporting requirements. The Agency notes that this action is limited to establishing reporting requirements, so the commenter's asserted support for actions to phase out use of ODS as process agents are beyond the scope of this action.

Another commenter requested that EPA revise the annual reporting timeline to provide consistency with prior practice, allow time for necessary information to become available, and avoid conflicting with other EPA deadlines. Specifically, the commenter requested that EPA revise the date by which annual reports must be submitted each year, from February 14 to July 31, or April 30 at the earliest. The commenter stated that previous requests for information from EPA on these process agent uses have been received in July and responses were due within 20 working days and that the proposal did not indicate a need or reason to vary this timeline. The commenter stated that information EPA proposed to require in the annual reports would not be available by February 14 and that this accelerated timeline would place an undue burden on the commenter. The commenter stated that manufacturing facilities that will be subject to the requirements being established in this rule will not have finalized emission calculations for the prior calendar year by February 14, and provided as examples that reporting under the Toxics Release Inventory (TRI) program is not due until July 1 and emission inventory reporting obligations for the commenter's facilities under State programs ranged from April 1 to April 30. The commenter stated that aligning the timing with other existing and established requirements would reduce burden associated with the proposed reporting obligations. The commenter cited identical rationales for asserting that data elements are confidential as it had for the proposed one-time reporting requirements.

EPA disagrees with the commenter's assertions that a February 14 deadline for annual reporting would be infeasible, unduly burdensome, or unjustified. The commenter did not explain why the information required to be included in the annual report would not be available by February 14. The commenter provided examples of later deadlines under different programs, but did not provide a reason that it would be infeasible for facilities to submit the required information for this program by February 14 of each year. Emissions of controlled substances from process agent uses are one component of overall emission inventories for subject

facilities and EPA is unaware of any impact the requirements being finalized in this action may have on these facilities under other programs. As EPA stated at proposal, February 14 aligns with the fourth quarter and annual deadlines for existing ODS reporting requirements under 40 CFR part 82. February 14 also aligns with existing deadlines for regulated substances, including reporting requirements under 40 CFR part 84 for hydrofluorocarbon (HFC) production (which includes emissions), HFC-23 emissions, and HFC process agent emissions. The commenter noted that it was subject to existing reporting deadlines that ranged from April 1 to July 1, and it is unclear why the commenter requested the requirements being finalized in this action should be no later than July 31, or, at the earliest, April 30. Furthermore, in line with U.S. commitments through the Montreal Protocol, the earlier reporting deadline being finalized supports EPA efforts to thoroughly review submitted information for completeness, accuracy, and consistency prior to a timely submission of this information to the Montreal Protocol's Ozone Secretariat on behalf of the United States. However, EPA is finalizing that the Agency may grant a short extension in the unlikely event that an entity cannot comply with this reporting timeline. Entities may submit a request for an extension with supporting documentation and explanation of the reasons needed for an extension. The Agency will consider the circumstances of any such requests and act accordingly. EPA addresses comments concerning the confidentiality determinations in section IV.B of this preamble.

C. Advance Notice of Changes Report

EPA is largely finalizing as proposed a requirement that entities provide advance notice of changes, with revisions to the conditions under which reporting would be necessary. This advance notice of changes is required at least 180 days before an entity expects to increase, as compared to the previous year and the average of the three previous years, the amount of process agent introduced into the application by more than 20 percent or emissions by at least one metric ton and 20 percent. EPA understands that facility operations change over time, and the Agency can monitor such changes through the annual reporting mechanism. However, large changes in facility operations over a short period of time can impact the environment, conformance with domestic regulatory requirements, and our commitment to international

agreements. Annual reports represent a delayed view into past actions and may not provide sufficient lead time for an appropriate response. This notification requirement will provide EPA the opportunity to assess potential implications in advance of a change at the facility.

EPA proposed to require that each facility with a significant process change, including an increase in the quantity of the final output manufactured using an ODS process agent, submit a report specifying changes at least 180 days prior to implementing the change. EPA proposed that this prior notification requirement apply to any process changes anticipated to result in increases by the next annual report of greater than 20 percent of the amount of controlled substance initially introduced for or emitted during use as a process agent by a facility, as compared to the corresponding data in the previous calendar year.

One commenter supported EPA's proposal to require reporting to specify changes at least 180 days before implementing a significant process change, including any increase in the quantity of manufacturing output using an ODS process agent. EPA acknowledges the commenter's support.

Another commenter requested that EPA not require the significant change report or, alternatively, that the reporting requirement exclude changes due to production variability and unexpected circumstances. The commenter offered examples of potential changes that may be difficult to predict with at least 180-day notice or where further revisions may occur after a notification is submitted, including plant outage(s), natural disasters, and market conditions. The commenter further stated that uses of process agents can be quite small and that a 20 percent change could be difficult to predict. The commenter suggested that, particularly for facilities that emit greater than one ton, EPA could require reporting of these changes in the annual report through which process agent use and emissions would already be reported.

EPA acknowledges the commenter's concerns about situations where the proposed requirements may be difficult to implement, but disagrees with the commenter's suggestion that the Agency not finalize the requirement to report significant changes in advance. It is unclear how the examples the commenter provided, namely plant outage(s), downtime due to natural disasters, other pauses in production, and drops in demand and production

due to the covid epidemic, would result in unanticipated large increases in process agent use or emissions. These are cases where process agent use and emissions may decrease by large quantities, but these decreases would not necessitate an advance notice of changes. Subsequent increases in use or emissions in a year following such unexpected cases might necessitate reporting, but after such incidents it would be reasonable to anticipate a return to previous production levels.

EPA could also imagine that unexpected changes at one of a company's facilities might result in increased utilization of one or more of its other facilities. Shifting production between facilities to account for such cases might result in an individual facility increasing its process use or emissions by large amounts, but not result in an overall increase across the company or the United States. This scenario would be unlikely to result in large impacts on total use and emissions, conformance with domestic regulatory requirements, or U.S. commitments under the Montreal Protocol. Therefore, EPA is revising the advance notice of changes reporting requirement so that it applies to each entity rather than to an individual facility. Additionally, the Agency is revising the basis of the percentage change to apply only if the increase is greater than a 20 percent increase relative to values from both the immediately previous year and the average of the past three years. This accounts for situations where production may drop in a single year and then return to typical levels in the following year, which would result in an apparent year-on-year increase. In this case it would be reasonable to expect that production may return to previous levels after a disruption. This also addresses cases where production may moderately increase annually, which would result in a relatively large increase over several years. EPA would receive relevant information each year and there would not be a large increase in any given year. In both cases advance notice would not be necessary for EPA to understand the potential for large increases and impacts by the submission of the next annual report. Furthermore, the Agency would have had opportunities to assess the circumstances and request additional information as relevant. Advance notice reporting will only be required for anticipated changes that represent a large overall increase for the entity, as calculated across all the entity's applicable facilities. EPA expects that

this mitigates the commenter's concern about production variability at the facility level or other unanticipated changes raised by the commenter. At the same time, the reports will provide EPA the information it needs to monitor uses and emissions of process agents. The Agency also recognizes that there may be instances where it is not feasible to provide EPA with the requisite 180 days of notice, but the possibility of those instances is not, in the Agency's view, a reason not to require the notice period. If that situation were to occur, EPA encourages the entity to contact the Agency as soon as practicable so that EPA can work with the entity.

EPA acknowledges the commenter's statement that a 20 percent change from a facility with relatively small emissions may be difficult to assess, but the Agency disagrees with the commenter's alternative recommendation that these changes instead be included in the annual report. Smaller changes at that level would pose lesser contributions to overall emissions in the United States, and advance notice would be less necessary. The annual report is submitted by February 14 of the year following actions taken, and is inherently retrospective. Only including this information in the annual report would defeat the purpose of providing advance notice. However, EPA recognizes that changes in emissions from process agents from facilities that have, on the whole, relatively small emissions, pose lesser contributions to overall emissions in the United States, and advance notice of these changes is therefore less critical.

Accordingly, EPA is revising the qualifying criteria to require that this advance notice be provided only where changes that would result in annual increases greater than 20 percent of the amount initially introduced or, for emissions, increases of at least 20 percent and one metric ton. This will ensure the Agency has advance notice of changes that may have a large impact on overall use or emissions of process agents in the United States, while exempting from the advance notice requirements changes from smaller contributors. EPA addresses comments concerning the confidentiality determinations in section IV.B of this preamble.

D. Emissions Reporting Methodology and Incorporation by Reference

In alignment with the one-time and annual reporting requirements being finalized in this action, EPA is establishing requirements that entities using controlled substances as process agents report emissions as specified in

40 CFR 84.25. These requirements are being finalized largely as proposed, with the addition of a mass balance compliance option and a revision of the retesting frequency to be at least every five years rather than every 10 years. The units of measure for determining emissions and the method to calculate emissions will be in kilograms of controlled substance emitted. Emission reporting requirements align as appropriate with timelines for one-time and annual reporting requirements being established in this action.

These requirements prescribe emission estimation methodologies through vent-specific and mass balance compliance options. Associated reporting and recordkeeping requirements will support EPA's efforts to validate the reported information. For example, for facilities using an emission factor-based method, each process vent in the top quartile of its respective facility's emissions generally must use the process-vent-specific emission factor method, which requires emission tests with process activity parameters measured for either each operating scenario or the operating scenario with the largest overall emissions. All emissions test data and procedures used in developing emission factors must be documented. Process vents with less emissions may use the process-vent-specific emission calculation factor method, which prescribes certain procedures to calculate emissions for each operating scenario, but does not require testing. All data, assumptions, and procedures used in the calculations or engineering assessment must be documented. Each process using the mass balance method must demonstrate adherence to accuracy and precision requirements. In these cases, the reported information follow specified methodologies and EPA may request and assess detailed records to better understand the reported data. EPA is also listing and incorporating by reference certain American Society of Mechanical Engineers (ASME), ASTM International (ASTM), and EPA standards as acceptable options to calculate, measure, analyze, or measure parameters associated with emissions. Due to similarities in requirements, emitted chemicals, and regulated industries, these standards are the same standards listed in 40 CFR part 98, subpart L, and the same versions incorporated by reference in 40 CFR 98.7, except for ASTM D6348–03,⁸

incorporated by reference in 40 CFR 60.17, and ASME MFC–4M–1986 (Reaffirmed 2016).⁹

EPA proposed to require that entities using controlled substances as process agents report emissions using a methodology similar to the emissions reporting requirements for the Greenhouse Gas Reporting Program (GHGRP) codified at 40 CFR part 98, subpart L (40 CFR 98.120 through 98.128). EPA also sought comment on a description of procedures to implement the proposed emission reporting requirements (available in a memorandum to the docket for this action at Docket ID No. EPA–HQ–OAR–2022–0707–0002).

Specifically, EPA proposed that acceptable testing methods for measuring process vent emissions of controlled substances would include EPA Method 18 in appendix A–1 to 40 CFR part 60, EPA Method 320 in appendix A to 40 CFR part 63, EPA 430–R–10–003, ASTM D6348–03, or other analytical methods validated using EPA Method 301 in appendix A to 40 CFR part 63. EPA Method 301 provides a process to validate and approve other analytical methods as appropriate. In the memorandum to the docket, EPA included as compliance options these and other methods listed for existing requirements in 40 CFR part 98, subpart L, and incorporated by reference in 40 CFR 98.7.¹⁰

In the proposal, EPA discussed advantages and disadvantages of potential approaches, requested comment on these assessments, and highlighted particular areas of consideration. The Agency noted the approach used by the TRI program at 40 CFR part 372, and explained its concerns with applying the general TRI reporting requirements to this limited set of ODS process agent pollutants, industry sectors, and types of operations for the purposes of this action.

Two commenters expressed their support for an emissions reporting approach similar to the GHGRP instead of TRI reporting requirements. There were no responses to EPA's request for

comment on whether adjustments from the proposed methodology were necessary to account for distinctions between controlled substance emissions, process agent applications, or industry sectors. The Agency understands that the emission reporting methodology established in this rule is applicable to these process agent applications and their associated industry sectors.

The Agency requested comment on whether there are potential gaps in the proposed approaches to determining emissions from process agent applications and whether alternative approaches, such as a mass balance method as described in appendix A to 40 CFR part 98, subpart L, may be suitable in those particular cases. EPA also requested comment on the advantages and disadvantages of specifying one testing method instead of several options (e.g., EPA Method 18 as the analytical method and EPA Method 21 monitoring procedures for leak detection). EPA sought comment on whether finalizing the use of one method, instead of multiple methods, would improve the consistency of emission data reported across the facilities using ODS as process agents.

Two commenters supported EPA's proposal to use a methodology similar to the emissions reporting requirements at 40 CFR part 98, subpart L. These commenters stated that it would be reasonable to allow only one testing method for this small set of affected entities instead of several options and that this would ensure more consistency when evaluating emissions. One of these commenters recommended that EPA finalize the rule as proposed. The commenter stated that the GHGRP approach is more reasonable than the TRI approach because it would require entities to use a specific methodology and report more detailed information, which would result in data that are more consistent and manageable for EPA to validate. The commenter further stated that the approach EPA proposed is more likely to produce more reliable emission data than the mass balance approach the Agency took comment on. The other commenter stated that more frequent and involved testing was necessary to ensure accurate accounting of emissions. Further, the commenter referenced a report that it had previously issued and stated that the report had demonstrated that the GHGRP reporting requirements, which rely on emission factor estimates and/or limited and infrequent testing to support calculation methods, may be insufficient to accurately estimate and account for the controlled substances

standard is the same standard listed in 40 CFR part 98, subpart L.

⁹ The version of ASME MFC–4M–1986 (Reaffirmed 2016) incorporated by reference in this action is different from the version listed in 40 CFR 98.7 but the standard is the same standard listed in 40 CFR part 98, subpart L.

¹⁰ As discussed in footnotes 8 and 9, in this action EPA is incorporating by reference different versions of standards than were listed in the memorandum. The Agency is also not incorporating by reference the ASTM D–2879 standard that was listed in the memorandum because it is unnecessary for the note's guidance to incorporate that standard by reference.

⁸ The citation for the version of ASTM D6348–03 incorporated by reference in this action is different from the citation listed in 40 CFR 98.7 but the

being emitted. Specifically, the commenter pointed to the report's assertion that its investigators detected controlled substances that the facilities did not report under existing GHGRP requirements. The commenter recommended incorporating some form of mandatory continuous emissions monitoring systems (CEMS) technology for the top emission sources of ODS process agents to gauge the accuracy of emission factor-based calculations and to identify emissions that may not have otherwise been detected. The commenter cited examples of technologies to continuously monitor emissions from process vents and leaks, including a portable Fourier-transform infrared spectroscopy (FTIR) gas analyzer and continuous infrared monitoring. The commenter stated that the frequency of retesting should be increased from every 10 years as proposed to every year to more quickly identify potential discrepancies between reported and actual emissions. The commenter stated that it is reasonable to expect monitoring and testing on all processes, given the restrictions on these ODS due to their outsized damage to the atmosphere. The commenter asked for clarification if TRI emission data would continue to be submitted in addition to these newly established requirements for ODS process agents. The commenter stated its belief in the value of a central data-sharing repository to view all fluorinated gas emission data and account for potential overlaps between reporting requirements. The commenter further stated that previous years' data on process agent raw volumes of emissions specific to each use and substance by facility reported to the Montreal Protocol should be available. The commenter suggested that the decline in the number of ODS process agent uses and emissions over the years indicates that these uses are not essential and will cease in the future with the rise of alternatives. The commenter urged EPA to use information gathered to advance the understanding of alternatives to ongoing ODS process agent uses, and available options to further limit emissions from those sources still requiring their use.

EPA acknowledges the commenters' support for the proposed methodology and one commenter's support for the proposal as a whole. The Agency acknowledges the commenters' general support for specifying one testing method instead of allowing any of the several methods that were proposed. No commenters indicated potential disadvantages with specifying EPA

Method 18 as the analytical method and EPA Method 21 monitoring procedures for leak detection. However, EPA remains unaware of whether these methods may be applicable in all situations for these operations and process agent emissions. At this time, EPA will allow entities to use any of the several methods being finalized in this action, as applicable. EPA will further assess available information and may consider in a future rulemaking whether it would be practicable and advisable to specify a more limited set of testing methods and monitoring procedures. To align with existing EPA emission reporting requirements for similar chemicals and processes, the Agency is incorporating by reference in 40 CFR part 82, subpart A, the same versions of the relevant methods listed at 40 CFR part 98, subpart L.

With respect to the commenter's request to require CEMS or some other form of continuous monitoring in order to verify the emission factor-based calculations underlying the proposed reporting requirements, EPA does not agree that these additional monitoring requirements and associated compliance burden are warranted for these circumstances. The Agency disagrees with the commenter's characterization of the report's findings as undermining the emission factor-based method or structure of the GHGRP reporting requirements in general as applied in this context for estimating emissions of controlled substances used as process agents. EPA's understanding is that the facility where the commenter detected CFCs does not use controlled substances as process agents and would not be subject to the requirements being established in this action. The commenter did not justify why the emissions it detected from that facility would indicate that the proposed methodology would be insufficient for the process agent uses addressed in this action. The fact that controlled substances were detected from the specific facility but not reported through the GHGRP does not indicate any inadequacies of the emission calculation, monitoring, or reporting requirements being established for process agent uses in this action. EPA explicitly excepted ODS controlled substances from the definition of "fluorinated greenhouse gas" under 40 CFR 98.6, and accordingly from the GHGRP emission reporting requirements under 40 CFR 98.122, because EPA already regulated controlled substances under 40 CFR part 82.¹¹ This exclusion of controlled

substances from the GHGRP reporting requirements was not due to any technical limitations of the requirements under 40 CFR part 98. EPA also understands that these facilities may produce or transform controlled substances, and other facilities within the vicinity may contribute to emissions of controlled substances as well, so it is unclear how effectively the detected emissions and recommended monitoring techniques may be attributable to any particular process. The emissions reporting requirements in this rule are specifically focused on obtaining accurate and consistent information on process agent uses. Because these process agent uses typically involve legacy operations, EPA does not anticipate that operations will change frequently enough in kind or scale to necessitate intensive monitoring or annual testing of process vents to revise emission factors. EPA is finalizing as proposed a requirement that entities conduct an emissions test of process vents to update emission factors if changes to operating scenarios result in increases of 15 percent or more. It is the Agency's view that this is adequate to ensure that emissions factors are accurate and reasonably reflect current conditions. Furthermore, while the Agency does not agree that annual retesting should be required, because, as noted, most of the process agent uses involve legacy operations where EPA does not anticipate much variability in operations, the Agency recognizes that retesting at a greater frequency than every 10 years would provide more assurance of the validity of these factors. Accordingly, in this final rule, EPA is requiring process vent testing, as applicable, no less often than every five years.

Another commenter stated that there are instances where a mass balance approach may be more accurate to estimate fugitive emissions than the proposed approach. The commenter provided information about its operations at one facility as an example, and requested EPA include a mass balance approach as an acceptable method for calculating fugitive ODS emissions. The commenter stated that, while the proposed emission factor-based methods have historically been used to quantify equipment leak emissions from various industrial processes, these approaches include factors that are based on general industry-wide data and do not necessarily reflect individual facility, site-specific process and equipment characteristics. The commenter explained that ODS enter into the

¹¹ 74 FR 16579.

process at its facility from a single source, the facility does not produce or transform the ODS, stack emissions are monitored with an EPA-certified CEMS, and the ODS content of all generated waste stream quantities are monitored and documented. For these circumstances, the commenter stated that the fugitive emissions would be underestimated using an emissions factor method and are more accurately calculated using a mass balance approach than Method 21 and screening level emission factors.

EPA understands that the proposed emission methodology requirements would be applicable to the commenter's operations and does not agree that these requirements lack adaptability to site-specific circumstances. The requirements being established in this action include a process to create site-specific process-vent-specific emission calculation factors and site-specific leak monitoring approaches. However, EPA acknowledges that a mass balance approach may also be an appropriate option for the situation described, which EPA understands to involve batch operations with no on-site production or transformation. Accordingly, EPA is adding a mass balance approach as a compliance option for batch operations with no on-site production or transformation of controlled substances, based on the GHGRP provisions listed in appendix A to subpart L of 40 CFR part 98. The GHGRP requirements were designed for situations where fluorine enters a process as part of a reactant and leaves as part of a product or byproduct. Controlled substances are not produced or transformed in these process agent applications. Accordingly, the mass balance approach established in this action for controlled substances used as process agents addresses the quantities of controlled substances entering and leaving the process agent application. Any entity that uses this compliance option must demonstrate that it can meet the error limits or measurement and operating criteria specified in the requirements. Each facility should use the methodology that most accurately estimates emissions from its processes.

More information on the standards being incorporated by reference in 40 CFR 82.27 is available in section VII.I of this preamble. Available ASME methods are ASME MFC-3M-2004, Measurement of Fluid Flow in Pipes Using Orifice, Nozzle, and Venturi; ASME MFC-4M-1986 (Reaffirmed 2016), Measurement of Gas Flow by Turbine Meters; ASME MFC-5M-1985 (Reaffirmed 1994), Measurement of Liquid Flow in Closed Conduits Using

Transit-Time Ultrasonic Flowmeters; ASME MFC-6M-1998, Measurement of Fluid Flow in Pipes Using Vortex Flowmeters; ASME MFC-7M-1987 (Reaffirmed 1992), Measurement of Gas Flow by Means of Critical Flow Venturi Nozzles; ASME MFC-9M-1988 (Reaffirmed 2001), Measurement of Liquid Flow in Closed Conduits by Weighing Method; ASME MFC-11M-2006), Measurement of Fluid Flow by Means of Coriolis Mass Flowmeters; and ASME MFC-14M-2003, Measurement of Fluid Flow Using Small Bore Precision Orifice Meters.

The ASTM method is ASTM D6348-03, Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy. ASTM D2879-97 (Reapproved 2007), Standard Test Method for Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope may also be used to determine vapor pressures for purposes of the definition "in light liquid service." ASTM D2879-97 is available for inspection at U.S. EPA's Air and Radiation Docket; EPA West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 202-566-1742 and may be obtained at ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428; phone: 610.832.9500; email: service@astm.org; website: www.astm.org/.

EPA methods are Approved Alternative Method 012: An Alternate Procedure for Stack Gas Volumetric Flow Rate Determination; Methods for Estimating Air Emissions from Chemical Manufacturing Facilities, Emissions Inventory Improvement Program, Volume II: Chapter 16, August 2007; EPA-453/R-95-017, November 1995; EPA-430-R-10-003, March 2010, Protocol for Equipment Leak Emission Estimates; and Other Test Method 24, September 2006, Tracer Gas Protocol for the Determination of Volumetric Flow Rate Through the Ring Pipe of the Xact Multi-Metals Monitoring System.

E. Recordkeeping

Entities are obligated under existing requirements to record information in accordance with 40 CFR 82.13 and 82.24, including information concerning ODS used as process agents. In this action EPA is finalizing as proposed recordkeeping requirements specifically for uses of ODS as process agents. Under 40 CFR 82.13(d), entities must retain the records and copies of reports required for at least three years. Under previously established requirements in 40 CFR 82.13 and 82.24, entities, including

producers and importers, must record information that applies to controlled substances in general, including those used as process agents. In this action EPA is establishing specific requirements that differentiate controlled substances intended for process agent use from the wider uses. This additional information will provide further distinctions of information already required to be recorded.

EPA proposed to also require that entities using process agents record information that documents what would be reported to the Agency, which includes information concerning sourcing, production, recycling, reuse, transformation, and destruction for ODS intended to be used for process agent applications.

Specifically, the Agency proposed to add requirements that companies that use process agents maintain: dated records of the quantity of each process agent produced at each facility; records identifying the producer or importer of process agents received; copies of invoices or receipts documenting the sale or other transfer of ownership of process agents; dated records identifying the quantity of each product manufactured within each facility by using process agents; dated records of the quantity of process agent spills or releases greater than or equal to 100 pounds; dated records of information used to calculate emissions; dated records of the quantity of process agents which are subsequently transformed or destroyed; and a copy of the transformation or destruction verification in the case that a process agent is subsequently sold or distributed to another entity for transformation or destruction.

One commenter requested that EPA revise the proposed reference to recordkeeping responsibility in 40 CFR 82.13(ee)(3) from applying to a "person" to instead apply to an "entity," in alignment with EPA's terminology for proposed reporting requirements under 40 CFR 82.13(ee)(1) and (2). The same commenter requested that EPA revise the recordkeeping requirements proposed in 40 CFR 82.13(ee)(3)(i) to reflect the amount of controlled substance used as process agent at each facility instead of the amount of controlled substance produced at each facility, as the commenter also produces the same controlled substance for other uses. The commenter stated that it would be difficult to predict or keep accurate numbers prospectively recording the amount of controlled substance that was produced and may be used as a process agent, and that

dated records of the amount used at each facility as a process agent would be most relevant for the purposes of these requirements.

As EPA states in footnote 2 of this preamble, “person” and “entity” may be used interchangeably in certain circumstances. The instances referenced were not intended to carry a material distinction in interpretation or application. For clarity, EPA is finalizing terminology in 40 CFR 82.13(ee)(3) that refers to the recordkeeping obligations as applying to an “entity.” To be clear, each entity, including all commonly owned companies, is responsible for the regulatory obligations as applicable of all commonly owned facilities and plants subject to the requirements being finalized in this action. EPA acknowledges the commenter’s explanation of its process agent production operations and understands that the same chemical may be used for multiple purposes and, after use as a process agent, may subsequently be transformed or destroyed. The Agency agrees that the amount of process agent used is a relevant recordkeeping element to track the use of controlled substances and is finalizing that additional data element for the recordkeeping requirements. However, under existing requirements in 40 CFR 82.13(f)(2)(ii) and 82.24(b)(1)(i) and (ii), entities must differentiate production records by whether the quantities of controlled substances were intended for use in processes resulting in their transformation or destruction. EPA understands that some quantities of controlled substances are produced solely for use by the same entity as a process agent and ultimately are not transformed or destroyed. The Agency understands that complete information on future use and disposition may not be known at the time of production, but sees value in documentation of the expected use. Therefore, in addition to requiring that entities maintain records of the quantities of each controlled substance initially introduced into the process agent application for use as a process agent, EPA is clarifying records of the quantity that was produced for use as a process agent refers to the expectation at the time of production. This requirement for entities that use process agents is separate from existing requirements for producers in 40 CFR 82.13(f)(2)(ii) and 82.24(b)(1)(i) and (ii) and may not necessarily correspond directly with the quantities actually used as a process agent.

IV. How will EPA treat ODS process agent data collected under this action?

Consistent with EPA’s commitment to transparency in program implementation, as well as to proactively encourage compliance with EPA’s general ODS phaseout and to meet the United States’ reporting commitments under the Montreal Protocol, EPA is finalizing determinations for the treatment and release of data that will be collected.

EPA is finalizing certain categorical emission data and confidentiality determinations for individual reported data elements that EPA will be collecting through this rulemaking. This action identifies certain information categories that must be submitted to the Agency that will be subject to disclosure to the public without further notice because the information has been determined to be either “emission data” under 40 CFR 2.301(a), or EPA has found that the information does not meet the standard for confidential treatment under Exemption 4 of the FOIA. The Agency has also identified certain other categories of information that may be entitled to confidential treatment. The emission data and confidentiality determinations in this action are intended to encourage consistency among reported data, compliance with EPA’s ODS phaseout, and to meet the United States’ reporting commitments under the Montreal Protocol. Establishing these determinations through this rulemaking will provide predictability for both information requesters and submitters. Separately, for information reported on process agents that is not addressed in this rulemaking, *i.e.*, data elements being finalized in this rule for which EPA is not in this action issuing a determination, the Agency will apply the 40 CFR part 2 process for establishing case-by-case confidentiality determinations.

A. Background on Determinations of Whether Information Is Entitled to Treatment as Confidential Information

1. Confidential Treatment of Reported Information

Regulated entities that must submit information to EPA frequently claim that some or all of that information is entitled to confidential treatment and therefore exempt from disclosure under Exemption 4 of the FOIA.¹² Exemption 4 exempts from disclosure “trade secrets and commercial or financial information obtained from a person [that is]

privileged or confidential.”¹³ In order for information to meet the requirements of Exemption 4, EPA must find that the information is either: (1) A trade secret, or (2) commercial or financial information that is: (a) obtained from a person, and (b) privileged or confidential.

Generally, when EPA has information that the Agency intends to disclose publicly that is covered by a claim of confidentiality under FOIA Exemption 4, EPA has a process to make case-by-case or class determinations under 40 CFR part 2 to evaluate whether such information qualifies for confidential treatment under the exemption.^{14 15} In this action, EPA is making categorical emission data and confidentiality determinations in advance through this notice and comment rulemaking for some information that will be submitted to EPA under the requirements established in this action. This information will be subject to disclosure to the public without further notice.

The U.S. Supreme Court decision in *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356 (2019) (*Argus Leader*) addresses the meaning of “confidential” within the context of FOIA Exemption 4. The Court held that “[a]t least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is ‘confidential’ within the meaning of Exemption 4.”¹⁶ The Court identified two conditions “that might be required for information communicated to another to be considered confidential.”¹⁷ Under the first condition, “information communicated to another remains confidential whenever it is customarily kept private, or at least closely held, by the person imparting it.”¹⁸ The second condition provides that “information might be considered confidential only if the party receiving it provides some

¹³ 5 U.S.C. 552(b)(4).

¹⁴ 40 CFR 2.205.

¹⁵ This approach of making categorical determinations for a class of information is a well-established Agency practice. Prior examples of rules where EPA has made such categorical determinations include Confidentiality Determinations for Data Required Under the Mandatory Greenhouse Gas Reporting Rule and Amendments to Special Rules Governing Certain Information Obtained Under the Clean Air Act (76 FR 30817, May 26, 2011); Control of Air Pollution From New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards (88 FR 4296, January 24, 2023); and Renewable Fuel Standard (RFS) Program: RFS Annual Rules (87 FR 39600, July 1, 2002).

¹⁶ *Argus Leader*, 139 S. Ct. at 2366.

¹⁷ *Id.* at 2363.

¹⁸ *Id.* (internal citations omitted).

¹² 5 U.S.C. 552(b)(4).

assurance that it will remain secret.”¹⁹ The Court found the first condition necessary for information to be considered confidential within the meaning of Exemption 4, but did not address whether the second condition must also be met.

Following the issuance of the Court’s opinion in *Argus Leader*, the U.S. Department of Justice issued guidance concerning the confidentiality prong of Exemption 4, articulating “the newly defined contours of Exemption 4” post-*Argus Leader*.²⁰ Where the Government provides an express or implied indication to the submitter prior to or at the time the information is submitted to the Government that the Government would publicly disclose the information, then the submitter generally cannot reasonably expect confidentiality of the information upon submission, and the information is not entitled to confidential treatment under Exemption 4.²¹ In this rule, EPA is clearly asserting the Agency’s determination that certain information is not confidential, not entitled to confidential treatment, and may be disclosed publicly. This is aligned with the Supreme Court’s decision and the subsequent Department of Justice guidance that the government’s assurances that a submission will be treated as *not* confidential should dictate the expectations of submitters. Based on the finalized determinations, submitters are on notice before they submit any information that EPA has determined that the identified data elements discussed below, as well as in the addendum provided in the docket for this action titled *Confidentiality Determinations and Emission Data Designations for Data Elements in the ODS Process Agents Reporting Final Rule*, will not be entitled to confidential treatment upon submission and may be released by the Agency without further notice. As a result, submitters will not have a reasonable expectation that the information will be treated as confidential; rather, they have the

reasonable expectation that the information will be disclosed.

As described further below, EPA is making categorical determinations that some of the data elements that will be submitted to EPA are not entitled to confidential treatment because either: it is not the type of information that submitters customarily keep private or closely held; it is already publicly available; or it is discernible information that is self-evident or readily observable through reverse engineering by a third party.

2. Emission Data Under Section 114 of the CAA

The CAA states that “[a]ny records, reports or information obtained under [section 114] shall be available to the public.”²² Thus, the CAA begins with a presumption that the information submitted to EPA will be available to be disclosed to the public. It then provides a narrow exception to that presumption for information that “would divulge methods or processes entitled to protection as trade secrets.” The CAA then narrows this exception further by excluding “emission data” from the category of information eligible for confidential treatment. While the CAA does not define “emission data,” EPA has done so by regulation at 40 CFR 2.301(a)(2)(i). On occasion EPA releases some of the information submitted under CAA section 114, such as emission data, to parties outside of the Agency of its own volition, through responses to requests submitted under the FOIA,²³ or through civil litigation. As noted in the prior section, generally, when EPA has information that the Agency intends to disclose publicly that is covered by a claim of confidentiality under FOIA Exemption 4, EPA has a process to make case-by-case or class determinations under 40 CFR part 2. This process includes an evaluation of whether such information is or is not emission data, and whether it otherwise qualifies for confidential treatment under FOIA Exemption 4.²⁴

The regulations at 40 CFR 2.301 define emission data to include the following:

- Information necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of any emission which has been emitted by the source (or of any pollutant resulting from any emission by the source), or any combination of the foregoing;

- Information necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of the emissions which, under an applicable standard or limitation, the source was authorized to emit (including, to the extent necessary for such purposes, a description of the manner or rate of operation of the source); and

- A general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

In this action, EPA is applying the regulatory definition of “emission data” in 40 CFR 2.301(a)(2)(i) to determine that certain categories of source certification and compliance information are not entitled to confidential treatment because they qualify as emission data. That information is subject to disclosure to the public without further notice. As relevant to this action, a “source” for purposes of the definition in 40 CFR 2.301 is generally the equipment covered by a regulatory requirement, such as process equipment in a plant or facility and any related emission units. EPA’s definition of emission data also excludes certain information related to products still in the research and development phase or products not yet on the market except for limited purposes. Thus, for example, 40 CFR 2.301(a)(2)(ii) excludes information related to “any product, method, device, or installation (or any component thereof) designed and intended to be marketed or used commercially but not yet so marketed or used.” This specific exclusion from the definition of emission data is limited in time. EPA has concluded that no data related to this exclusion are implicated in this rulemaking because data required to be reported under this rule generally relate to equipment that EPA understands are primarily for purposes of maintaining legacy production processes at existing facilities.

B. Data Elements To Be Reported to EPA Under This Action

Consistent with EPA’s commitment to transparency in program implementation, EPA has reviewed the data reporting elements being finalized in this action to see if information under the umbrella of those data elements could be considered entitled to confidential treatment. EPA is finalizing as proposed its determinations to treat

¹⁹ Id. (internal citations omitted).

²⁰ “Exemption 4 After the Supreme Court’s Ruling in *Food Marketing Institute v. Argus Leader Media* and Accompanying Step-by-Step Guide,” Office of Information Policy, U.S. Department of Justice, (October 4, 2019). Available at: <https://www.justice.gov/oip/exemption-4-after-supreme-courts-ruling-food-marketing-institute-v-argus-leader-media>.

²¹ See *id.*; see also “Step-by-Step Guide for Determining if Commercial or Financial Information Obtained from a Person is Confidential under Exemption 4 of the FOIA,” Office of Information Policy, U.S. Department of Justice, (updated October 7, 2019). Available at: <https://www.justice.gov/oip/step-step-guide-determining-if-commercial-or-financial-information-obtained-person-confidential>.

²² CAA section 114(c); 42 U.S.C. 7414(c).

²³ 5 U.S.C. 552.

²⁴ 40 CFR 2.301(a)(2)(i).

certain data elements as not entitled to confidential treatment. Later in this section, EPA outlines individual data elements and the Agency's determinations of whether they will be handled as confidential, not confidential or undetermined. The Agency also lists its determinations of whether the data elements are emission data, which are not confidential, and are therefore releasable. There may be additional reasons not to release individual data elements determined to not be entitled to confidential treatment, for example if it is personally identifiable information. EPA is making confidentiality determinations and treating data concerning process agent uses similarly to the process under the HFC Phasedown Program as codified in 40 CFR 84.31(k). Some data may be released in different contexts, including to the general public to encourage transparency, to ensure compliance with EPA's general ODS phaseout, and to meet the United States' reporting commitments under the Montreal Protocol. Emission data, including data used as inputs to emissions equations, is generally releasable under CAA section 114(c), which provides that emission data shall be available to the public. "Inputs to emission equations" refers to data necessary to determine the identity, amount, frequency, or concentration of the emission emitted by the reporting facilities. Inputs to emission equations include equipment parameters, measured data, supporting calculations, and other rationale used to calculate reported emission quantities. Some aggregated data would also be released to the Ozone Secretariat in line with past practices and existing commitments, which could include a list of the process agent applications and the specific ODS used as process agents in those applications, the levels of emissions from those process agent applications in metric tons and ODP-weighted metric tons, and the specific containment technologies used to minimize emissions of controlled substances. EPA also stated the Agency's intention to release the aggregate consumption of ODS used as process agents in metric tons and ODP-weighted tons. Finally, EPA stated that the Agency would include production, import, export, and destruction of ODS used as process agents by chemical in data reported to the Montreal Protocol's Ozone Secretariat as part of the United States' annual report submitted under Article 7 of the treaty. At this time, this aggregated data would generally comprise data from three or more entities. Release of this information

documents U.S. conformance with commitments under an international agreement, so even if the number of entities with process agent uses decreases in the future, EPA is determining that process agent data reported by the United States in accordance with commitments under the Montreal Protocol are not confidential.

Some of the data elements EPA is collecting may be similar to or the same as those required to be reported under the existing requirements associated with the GHGRP, particularly for entities subject to 40 CFR part 98, subpart L. Those reporting requirements are separate and the Agency is not making any changes to 40 CFR part 98 in this rulemaking. To the extent relevant, data elements submitted in accordance with requirements established through this rulemaking and determined to not be confidential under 40 CFR part 82, subpart A, will not be provided confidential treatment regardless of whether they have previously been determined to be confidential under the GHGRP.

Specifically, EPA proposed that the identity of byproducts manufactured in the process agent application; contact information for facilities that use controlled substances as process agents; emission data, including reported emission factors and the proposed ODS process agent monitoring plan; and technologies currently being used and actions taken to minimize use or emissions of controlled substances used as process agents would not be considered confidential. The Agency proposed in general, as described in more detail in a memorandum to the docket for this rulemaking, to determine the following information concerning ODS process agents as confidential: process agent sourcing; internal facility processes such as the quantity of process agent use, process agent recycling, process agent reuse, end products from the process agent application (e.g., chlorine from a chlor-alkali process), and byproducts (e.g., hydrogen from a chlor-alkali process); and emission reduction technologies and actions planned or currently under evaluation. As noted previously, the Agency expects to release aggregated data to the Ozone Secretariat, including ODS process agent information concerning process agent applications currently used in the United States, consumption, emissions, and emission reduction technologies and actions undertaken. Further, EPA would begin reporting emission data in metric tons instead of ODP-weighted metric tons.

One commenter supported EPA's proposal that data reported by the United States in accordance with commitments under the Montreal Protocol would not be confidential and stated that publishing this data is a requirement to assess the success of current emissions abatement technologies. The same commenter urged EPA to transparently share data on process agent emissions by specific use.

EPA acknowledges the commenter's support for the Agency's determination of the confidentiality of information submitted under the Montreal Protocol on behalf of the United States. The Agency reiterates that EPA may release and publish both data that has been determined to not be confidential and aggregated data derived from information that has been determined to be confidential. The Agency will further consider how such data may be shared.

Another commenter stated that certain data reporting elements established in this action, as addressed in sections III.A, III.B, and III.C of this preamble, meet the criteria to be considered confidential and requested that other elements that also meet those criteria may also be treated as confidential. The commenter requested that EPA confirm that the Agency will extend confidential treatment to all information submitted in the one-time and annual reports that meet FOIA exemptions. The commenter further stated that EPA should not preclude entities from claiming information as confidential in the reports if the item or process is not on EPA's list of items that should be identified as confidential information, but that does meet a FOIA statutory exemption. The commenter statements generally aligned with EPA's proposed confidentiality determinations.

In accordance with the process established in this action at 40 CFR 82.26, EPA is making determinations by rulemaking on data elements discussed in this section, as well as in the addendum provided in the docket for this action titled *Confidentiality Determinations and Emission Data Designations for Data Elements in the ODS Process Agents Reporting Final Rule*, about whether certain information is entitled to be treated confidentially. For information that must be reported as a result of this final rule for which EPA has not made a confidentiality determination, entities may claim the information as confidential and EPA will apply the 40 CFR part 2 process for case-by-case confidentiality determinations.

The commenter more specifically stated that percentages of class I controlled substances used as a process agent and retained, recovered, or entrained in the final product should be identified as confidential. The commenter noted that EPA had proposed to determine that information relating to internal process agent use, recycling, reuse, products, and byproducts would be confidential and requested that EPA clearly delineate that this information would be considered confidential. In support of its assertions, the commenter claimed that percentages and volumes, despite the few domestic manufacturers for some of the controlled substances, could reveal insights into a variety of sensitive considerations, including business decisions, production approaches, operational changes, and confidential manufacturing processes. The commenter specifically stated that percentages used as a process agent and then retained, recovered, or recycled, and the amounts of each product and byproduct manufactured during the prior control period, including the amounts destroyed or used as feedstock, are confidential. The commenter stated that there may be technologies or processes in place that reduce information (EPA understands the commenter as intending to refer to emissions) but are trade secrets or otherwise related to commercial information that qualify for exemptions as confidential under the Freedom of Information Act (FOIA).

As discussed in section III.A of the preamble, EPA disagrees that reported information on percentages of process agent used would disclose confidential information concerning overall production of the given controlled substances. The relevant data elements are, of the amount of controlled substance used as a process agent, what percentages in the process agent application were respectively retained, consumed, recovered, emitted, or entrained. These representative percentages of process agent use through a cycle of the process agent application would not compromise its manufacturing processes. With regard to the particular data elements, EPA acknowledges the commenter's support for its confidentiality determinations and determines, as proposed, that specific information related to internal processes, *i.e.*, the percentages retained within and recovered after the process agent application, and the amounts of each product and byproduct manufactured during the prior control period are confidential. The Agency also

determines, as proposed, that specific information related to emissions, *i.e.*, the percentages emitted from the facility or entrained in the final product, are not confidential. Additionally, EPA determines that the percentage consumed in the process agent application is not confidential. These determinations are listed in a memorandum to the docket for this rulemaking.

The commenter referenced EPA's proposed determinations of data elements for annual reports, including examples for internal facility processes. The commenter stated that this confidential information includes, but may not be limited to, information proposed to be submitted under 40 CFR 82.13(ee)(2)(iv) for the amount used as a process agent that was ultimately transformed, recycled, or destroyed, and under 40 CFR 82.13(ee)(2)(vi) for the amount of product and byproduct manufactured in the process agent application. The commenter further stated that production variability due to market variability is confidential, supported the Agency's proposed confidentiality determination concerning the proposed advance notice of change, and, if the requirements were to be finalized, encouraged EPA to confirm that the determination applies to information submitted in advance of a change.

EPA discusses comments concerning the annual report and advance notice of changes in sections III.B and C. of this preamble. As specified above in this section of the preamble, the Agency will treat the confidentiality of submitted information in accordance with its determinations by rulemaking. Entities may claim other information as confidential, and EPA will follow the process described in this section of the preamble. EPA acknowledges the commenter's support in general on the proposed confidentiality determinations and notes that the Agency is finalizing in this action a determination that the fact that an advance notice of changes was submitted is not confidential, but the changes themselves are confidential.

V. Definitions

EPA is finalizing a definition of "process agent" largely the same as the definition proposed, with the addition of a list explicitly including currently approved process agent uses, and is finalizing as proposed two definitions to better reflect current Agency and international practices. EPA is also adding definitions as part of the emission reporting requirements this action is establishing in 40 CFR 82.25.

EPA proposed to define the term "process agent" for the purposes of 40 CFR part 82 as "the use of a controlled substance to form the environment for a chemical reaction or inhibiting an unintended chemical reaction (*e.g.*, use as a solvent, catalyst, or stabilizer) where the controlled substance is not consumed in the reaction, but is removed or recycled back into the process and where no more than trace quantities remain in the final product. A feedstock, in contrast, is entirely consumed during the reaction." The Agency also proposed to switch the definitions of "facility" and "plant" in 40 CFR 82.3 to better align with how they would typically be understood and applied.

One commenter supported EPA's proposed definition of "process agent." EPA acknowledges the first commenter's support for the proposed definition of "process agent."

Another commenter suggested that specific measurable numerical thresholds for quantities retained in the final product or consumed during the reaction would provide regulatory clarity. The commenter recommended EPA define a residual concentration of process agent in a product as 0.01 percent by weight and to set a consumption rate of below one percent to distinguish a controlled substance used as a process agent from one use as a feedstock.

The Agency acknowledges the commenter's statement that including thresholds may provide additional clarity, but disagrees with the commenter's suggested changes. EPA did not propose numerical thresholds, the commenter did not provide supporting evidence to justify the particular suggested values, and it is not readily apparent what the appropriate thresholds for these process agent uses would be. In this action EPA is establishing reporting requirements for these process agent uses, including for information that would be relevant for further consideration of this issue. Specifically, as discussed in section III.A of this preamble, EPA is establishing requirements in the one-time report for companies to provide details of the amount of process agent used and of what percentages are subsequently retained within the process agent application, consumed during the process agent application, recovered after the process agent application, emitted, or entrained in the final product. EPA is not establishing numerical thresholds at this time, but will consider this information, as well as potential interactions with related

program areas, as relevant in any future determination the Agency may make.

A commenter who uses a controlled substance in a manufacturing process expressed concern that the definition EPA proposed could unintentionally exclude certain existing uses, including the commenter's use. The commenter noted that EPA had previously acknowledged that its use of a controlled substance constituted a process agent use, the same process agent use is listed in table A to decision XXXI/6, and the commenter has annually submitted information to EPA on this process agent use. For clarity and to include existing approved uses, this commenter recommended that the Agency revise the definition to reference, in addition to chemical changes, uses that result in forming the environment for or inhibiting an unintended physical change, and to specify a physical spinning/extruding process as an example. Alternatively, the commenter recommended to expand the definition to include any uses identified in the Technology and Economic Assessment Panel (TEAP)'s list of process agent usages, and included in Table A from a TEAP report.

EPA acknowledges the commenter's concerns that the text of the proposed definition of "process agent" could be interpreted to exclude existing process agent uses. The Agency understands, based on another TEAP report included in the comments, that the controlled substance in question is used as an extraction solvent associated with a chemical reaction process. EPA sought clarification from the commenter and confirmed that it does not use the process agent for other purposes. EPA did not intend in this definition to exclude existing process agent uses that EPA has previously recognized, as listed in footnote 6 to the proposed rule (88 FR 72030). However, EPA disagrees that it is appropriate or necessary to include physical changes in the definition. As EPA discussed in a similar context for HFC process agents (86 FR 55135), EPA does not have sufficient information to support a change. It is unclear what other processes might be included within that wider scope or what the potential implications may be of including physical changes in the definition. Furthermore, EPA does not agree that any uses listed by the TEAP should be incorporated into the definition. Table A, first established in decision X/14 and most recently updated in decision XXXI/6, includes all uses that have been permitted among the Parties to the Montreal Protocol, including those that have not been

approved for the United States. Table A may be subject to further updates by the Parties in the future, and EPA is aware that five of these uses continue in the United States. In this action EPA clarifies that the definition of "process agent" includes, but is not limited to, the use of the following controlled substances in the following process agent applications and therefore the existing use referenced by the commenter: the use of carbon tetrachloride in the elimination of nitrogen trichloride in chlor-alkali production, the use of carbon tetrachloride in the recovery of chlorine by tail gas absorption from chlor-alkali production, the use of CFC-11 in the production of synthetic fiber sheet, the use of bromochloromethane in bromination of a styrenic polymer, and the use of CFC-113 in the production of high modulus polyethylene fiber. This definition also includes any other uses of controlled substances that meet the functional criteria.

One commenter supported EPA's proposed definitions of "plant" and "facility." Another commenter stated that the Agency should change the term "plant" to "unit" or "process unit" because "plant" may be used synonymously as EPA's proposed definition of "facility." The commenter also stated that, in addition to process equipment, this definition should include a collection of process equipment.

EPA acknowledges the first commenter's support for the proposed definitions. In response to the second commenter, EPA recognizes that terminologies may vary between particular situations, the term "plant" may be used in similar contexts as "facility," the reference to process equipment could be applied more narrowly to a process unit, and that a plant would typically contain a collection or group of process equipment. However, multiple plants may be collocated within what is commonly considered a facility. These terms have particular relevance within EPA's domestic requirements and the Montreal Protocol. For example, in decision X/14 the Parties agreed, with certain conditions, that no new plants using the listed process agents would be installed or commissioned. This context more closely aligns with equipment associated with a process agent application than an overall industrial site. Similarly, a plant contains any process equipment associated with the relevant industrial operations. The definition of "plant" is intended to broadly encompass any individual piece or collection of equipment. EPA further

clarifies that this term includes any equipment that use controlled substances, such as process agents, related to industrial operations that convert raw materials, convert feedstock chemicals, or produce other chemicals. EPA is therefore not adopting the commenter's suggested changes to the definitions. Moreover, EPA expects the terminology, that is being finalized as proposed, will be clear for the limited set of entities subject to the requirements of 40 CFR part 82.

EPA is finalizing the definitions listed in the description of procedures to implement the proposed emission reporting requirements in 40 CFR part 82, subpart A. These definitions align with existing practice in 40 CFR part 98, subpart L, and the Agency did not receive comment on these definitions. The defined terms are: "batch emission episode," "batch process or batch operation," "byproduct," "continuous process or operation," "difficult-to-monitor," "dual mechanical seal pump and dual mechanical seal agitator," "equipment," "in controlled substance service," "in gas and vapor service," "in heavy liquid service," "in light liquid service," "in vacuum service," "isolated intermediate," "no external shaft pump and no external shaft agitator," "operating scenario," "process," "process condenser," "process vent," "typical batch," "uncontrolled emissions of controlled substances," and "unsafe-to-monitor."

VI. Costs and Benefits

The recordkeeping and reporting requirements EPA is establishing in this rule for uses of ODS as process agents in general codify existing practices and do not represent substantive additional effort on the part of affected entities. EPA is aware of six potentially affected entities, and expects that these entities are already able to meet most of the requirements based on current practice. These requirements will support U.S. efforts to report information consistent with Montreal Protocol decisions and to better understand potential implications of uses of ODS as process agents under the CAA.

EPA expects that entities that will be affected by this action are already subject to recordkeeping and reporting requirements under 40 CFR part 82 and that the requirements established in this action will not result in significant increased burden. In 40 CFR 82.13 and 82.24 the Agency had already required producers of controlled substance to record and report related information, including requirements in 40 CFR 82.13(f)(2)(vii) and 82.24(b)(2)(vi) to maintain records of any controlled

substance used as a feedstock, destroyed in the manufacture of another substance, used in the manufacture of any other substance, or introduced into the production process of the same controlled substance. EPA also requires documentation and reporting for uses of ODS in processes that result in their transformation or destruction. Subject entities have already reported similar information to EPA concerning uses of ODS as a process agent in the past on a voluntary basis, report similar information concerning production of ODS and feedstock uses, and already have available process knowledge and experience necessary to meet the recordkeeping and reporting requirements established in this action. The codified requirements will also reduce potential uncertainty about EPA's recordkeeping and reporting expectations.

This action will result in costs for each subject entity to prepare an initial one-time report, submit annual reports and notifications of significant changes as warranted, and recordkeeping. However, with regards to the annual reports, the Agency has historically solicited information from the affected entities via annual requests. Therefore, EPA expects any associated change in burden will be limited relative to past practice. The Agency conservatively estimates these requirements to result in costs of approximately \$13,000 per facility for the first year, with the higher costs due to initial preparation of the one-time report, and \$1,000 per facility in following years for continued compliance with the other recordkeeping and reporting requirements. As noted in section II.B. of this preamble, EPA does not anticipate the establishment of new processes or facilities using ODS as process agents. The Agency did not receive additional information on this assumption in response to a request for comment at proposal.

The Agency estimates that the annual emissions reporting requirements being finalized in this action, without accounting for past practice, will result in additional costs of approximately \$190,000 per facility in the first year due to initial planning and additional sampling, analysis, monitoring, and calculations. EPA estimates compliance costs of approximately \$17,000 in subsequent years for continued sampling, analysis, monitoring, and calculations. The total estimated costs for all requirements are approximately \$1.8 million in the first year and \$210,000 annually in subsequent years. The costs are discussed in the

supporting statement for the information collection request (ICR).

VII. Statutory and Executive Order Review

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 14094, and was therefore not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

The information collection activities in this rule will be submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number 1432.40. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

This ICR covers provisions under the Montreal Protocol and title VI of the CAA that establish limits on total U.S. production, import, and export of class I and class II ozone-depleting substances (or controlled substances). Production and import of class I controlled substances was phased out in the United States. The phaseout includes exceptions for essential uses, critical uses of methyl bromide, quarantine and pre-shipment uses of methyl bromide, previously used material, and material that will be transformed or destroyed. There are also regulations that restrict the use of class II controlled substances and require a gradual reduction in the production and consumption of these chemicals leading to their eventual phaseout. The class II controlled substance phaseout regulations include exceptions for previously used material and material that will be transformed or destroyed.

In this action, EPA is establishing requirements for one-time, annual, and situational reporting and for recordkeeping to provide relevant information to EPA concerning implications of process agent uses and emissions and support international agreements concerning the use of controlled substances as process agents. One-time reporting, annual reporting, and recordkeeping requirements are consistent with the existing requirements for importers and producers in 40 CFR 82.13 for class I controlled substances and 40 CFR 82.24 for class II controlled substances. These requirements are also consistent with

existing practice of facilities subject to this rule who have provided similar information to EPA concerning these uses of controlled substances as process agents. The ICR includes these incremental changes in addition to the existing reporting and recordkeeping programs that are approved under OMB control number 2060-0170.

Respondents/affected entities:

Producers, importers, exporters, and certain users of ozone-depleting substances, including as process agents; methyl bromide applicators, distributors, and end users including commodity storage and quarantine users.

Respondent's obligation to respond: Mandatory—sections 603(b), 604(d)(6), and 114 of the CAA.

Estimated number of respondents: 1,175.

Frequency of response: One-time, quarterly, annually, and as needed.

Total estimated burden: 8,905 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$1,122,911 (per year), including \$36,495 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

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 because none of the identified affected entities are small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million (in 1995 dollars, adjusted annually for inflation) or more 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 is less than \$100 million.

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. EPA is not aware of Tribal businesses engaged in activities that would be directly affected by this action. Based on the Agency's assessments, as discussed in section VI of this preamble, EPA also does not believe that potential effects, even if direct, would be substantial. Accordingly, this action will not have substantial direct effects on one or more Indian Tribes, the relationship between the Federal Government and Indian Tribes, or the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action. The Agency has updated Tribal officials on this air regulation through a monthly meeting of the National Tribal Air Association.

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

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. Therefore, this action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks. Since this action does not concern human health, EPA's Policy on Children's Health also does not apply.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act and Incorporation by Reference

This action involves technical standards. EPA has decided to allow the use of the following ASME, ASTM, and EPA standards as compliance options under the emission reporting requirements established in this action. These existing voluntary consensus standards were previously incorporated under the GHGRP in 40 CFR 98.7 to help facilities monitor, report, and keep records of GHG emissions. This version

of ASTM D6348–03 was previously incorporated by reference in 40 CFR 60.17 and the remaining standard versions, except for ASME MFC–4M–1986 (Reaffirmed 2016), were previously incorporated by reference in 40 CFR 98.7. ASME MFC–3M–2004 specifies the geometry and method of use for pressure difference devices which give necessary information for calculating flow rates and associated uncertainties. ASME MFC–4M–1986 (Reaffirmed 2016) specifies procedures to evaluate flow rates using turbine meters. ASME MFC–5M–1985 (Reaffirmed 1994) specifies procedures to evaluate flow rates using ultrasonic flowmeters that base their operation on the measurement of transit times of acoustic signals. ASME MFC–6M–1998 describes the use of vortex flowmeters to measure volumetric flow rate and total flow. ASME MFC–7M–1987 (Reaffirmed 1992) specifies the geometry and method of use for critical flow venturi nozzles. ASME MFC–9M–1988 (Reaffirmed 2001) specifies a method to calculate liquid flow rate and uncertainties by measuring the mass of liquid delivered into a weighing tank in a known time interval. ASME MFC–11M–2006 gives guidelines for the selection, installation, calibration, and operation of Coriolis flow meters for the determination of mass flow, density, volume flow, and other related parameters of flowing fluids. ASME MFC–14M–2003 specifies the geometry and method of use for orifice meters. The ASME standards are available for purchase from Two Park Avenue, New York, NY 10016, phone: 800.843.2763, email: CustomerCare@asme.org; website: www.asme.org. In this action EPA is incorporating by reference versions of these standards that are not available through the ASME website. These versions are available for purchase from private resellers, including Nimonik Document Center, 401 Roland Way, Suite 224, Oakland, CA 94624; phone (650)591–7600; email: info@document-center.com; website: www.document-center.com. The cost of an electronic copy is \$100 for ASME MFC–3M–2004, \$33 for ASME MFC–4M–1986 (Reaffirmed 2016), \$29 for ASME MFC–5M–1985 (Reaffirmed 1994), \$35 for ASME MFC–6M–1998, \$65 for ASME MFC–7M–1987 (Reaffirmed 1992), \$32 for ASME MFC–9M–1988 (Reaffirmed 2001), \$46 for ASME MFC–11M–2006, and \$40 for ASME MFC–14M–2003.

ASTM D6348–03 specifies a test method to quantify gas phase concentrations of target analytes by using extractive direct interface FTIR

spectroscopy. The ASTM International standard is available for purchase from ASTM International at 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428; tel.: 610.832.9500; service@astm.org; website: <https://www.astm.org/>. The cost of an electronic copy is \$83 for ASTM D6348–03. The cost of obtaining the applicable ASME and ASTM standards is not a significant financial burden.

EPA's Approved Alternative Method 012 specifies procedures to use a tracer gas to determine the stack gas volumetric flow rate when low velocities and temporal variations complicate measurement. The Emissions Inventory Improvement Program, Volume II: Chapter 16 provides methods for estimating air emissions from chemical manufacturing facilities. EPA–453/R–95–017 provides a protocol to generic process unit-specific estimates for equipment leak emissions. EPA–430–R–10–003 provides a protocol for two specific methods for measuring abatement system inlet and outlet flows, and hence destruction or removal efficiencies, for process equipment. EPA's Other Test Method 24 specifies a tracer gas procedure with a gas chromatograph and flame ionizer detector to measure the volumetric flow rate. The EPA standards are freely available from U.S. Environmental Protection Agency at 1200 Pennsylvania Avenue NW, Washington, DC 20460, 202.272.0167, <https://www.epa.gov>. Electronic copies are available at <https://www.epa.gov/sites/default/files/2020-08/documents/alt-012.pdf> for Approved Alternative Method 012; https://www.epa.gov/sites/default/files/2015-08/documents/ii16_aug2007final.pdf for Emissions Inventory Improvement Program, Volume II: Chapter 16, Methods for Estimating Air Emissions from Chemical Manufacturing Facilities, August 2007; https://www.epa.gov/sites/default/files/2020-09/documents/protocol_for_equipment_leak_emission_estimates.pdf, November 1995 for EPA–453/R–95–017; https://www.epa.gov/sites/default/files/2016-02/documents/dre_protocol.pdf, March 2010 for EPA 430–R–10–003; and <https://www.epa.gov/sites/default/files/2020-08/documents/otm24.pdf> for Other Test Method 24. Therefore, EPA concludes that the ASME, ASTM, and EPA standards being incorporated by reference are reasonably available.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

EPA believes that this type of action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to potentially disproportionate and adverse effects on communities with environmental justice concerns because it does not impact emissions from subject facilities. This regulatory action establishes reporting and recordkeeping requirements that do not impact human health or the environment, but provide additional insight into the uses and emissions of ODS used as process agents.

K. Congressional Review Act (CRA)

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

List of Subjects in 40 CFR Part 82

Environmental protection, Chemicals, Emissions, Incorporation by reference, Reporting and recordkeeping requirements.

Michael S. Regan,
Administrator.

For the reasons set out in the preamble, 40 CFR part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

■ 2. Amend § 82.3 by:

■ a. Adding the definitions of "Batch emission episode", "Batch process or batch operation", "Byproduct", "Continuous process or operation", "Difficult-to-monitor", "Dual mechanical seal pump and dual mechanical seal agitator", and "Equipment" in alphabetical order;

■ b. Revising the definition of "Facility";

■ c. Adding the definitions of "In controlled substance service", "In gas and vapor service", "In heavy liquid service", "In light liquid service", "In vacuum service", "Isolated intermediate", "No external shaft pump and no external shaft agitator", and

"Operating scenario" in alphabetical order;

■ d. Revising the definition of "Plant"; and

■ e. Adding the definitions of "Process", "Process agent", "Process condenser", "Process vent", "Typical batch", "Uncontrolled emissions of controlled substances", and "Unsafe-to-monitor" in alphabetical order.

The additions and revisions read as follows:

§ 82.3 Definitions for class I and class II controlled substances.

* * * * *

Batch emission episode means a discrete venting episode associated with a vessel in a process; a vessel may have more than one batch emission episode. For example, a displacement of vapor resulting from the charging of a vessel with a feed material will result in a discrete emission episode that will last through the duration of the charge and will have an average flow rate equal to the rate of the charge. If the vessel is then heated, there will also be another discrete emission episode resulting from the expulsion of expanded vapor. Other emission episodes also may occur from the same vessel and other vessels in the process, depending on process operations.

Batch process or batch operation means a noncontinuous operation involving intermittent or discontinuous feed into equipment, and, in general, involves the emptying of the equipment after the batch operation ceases and prior to beginning a new operation. Addition of raw material and withdrawal of product do not occur simultaneously in a batch operation.

* * * * *

Byproduct (for the purpose of this subpart only) means a chemical that is produced coincidentally during the production of another chemical.

* * * * *

Continuous process or operation means a process where the inputs and outputs flow continuously throughout the duration of the process. Continuous processes are typically steady state.

* * * * *

Difficult-to-monitor means the equipment piece may not be monitored without elevating the monitoring personnel more than 2 meters (7 feet) above a support surface or it is not accessible in a safe manner when it is in controlled substance service.

* * * * *

Dual mechanical seal pump and dual mechanical seal agitator means a pump or agitator equipped with a dual mechanical seal system that includes a

barrier fluid system where the barrier fluid is not in light liquid service; each barrier fluid system is equipped with a sensor that will detect failure of the seal system, the barrier fluid system, or both; and meets the following requirements:

(1) Each dual mechanical seal system is operated with the barrier fluid at a pressure that is at all times (except periods of startup, shutdown, or malfunction) greater than the pump or agitator stuffing box pressure; or

(2) Equipped with a barrier fluid degassing reservoir that is routed to a process or fuel gas system or connected by a closed-vent system to a control device; or

(3) Equipped with a closed-loop system that purges the barrier fluid into a process stream.

* * * * *

Equipment (for the purposes of § 82.25 only) means each pump, compressor, agitator, pressure relief device, sampling connection system, open-ended valve or line, valve, connector, and instrumentation system in controlled substance service for a process listed in § 82.25(b)(2); and any destruction units or closed-vent systems to which corresponding processes are vented.

* * * * *

Facility means one or more plants at the same location owned by or under common control of the same person.

* * * * *

In controlled substance service means that a piece of equipment that engages in an activity listed in § 82.25(b)(2), either contains or contacts a controlled substance that is a liquid or gas, and contains at least 5 percent by weight of a controlled substance.

In gas and vapor service means that a piece of equipment in regulated material service contains a gas or vapor at operating conditions.

In heavy liquid service means that a piece of equipment in regulated material service is not in gas and vapor service or in light liquid service.

In light liquid service means that a piece of equipment in regulated material service contains a liquid that meets the following conditions:

(1) The vapor pressure of one or more of the compounds is greater than 0.3 kilopascals at 20 °C;

(2) The total concentration of the pure compounds constituents having a vapor pressure greater than 0.3 kilopascals at 20 °C is equal to or greater than 20 percent by weight of the total process stream; and

(3) The fluid is a liquid at operating conditions.

Note 1 to definition of "in light liquid service": Vapor pressures may be determined by standard reference texts or ASTM D–2879.

In vacuum service means that equipment is operating at an internal pressure which is at least 5 kilopascals below ambient pressure.

* * * * *

Isolated intermediate means a product of a process that is stored before subsequent processing. An isolated intermediate is usually a product of chemical synthesis. Storage of an isolated intermediate marks the end of a process. Storage occurs at any time the intermediate is placed in equipment used solely for storage.

* * * * *

No external shaft pump and no external shaft agitator means any pump or agitator that is designed with no externally actuated shaft penetrating the pump or agitator housing.

* * * * *

Operating scenario means any specific operation of a process and includes the information specified in paragraphs (1) through (5) of this definition for each process. A change or series of changes to any of these elements, except for paragraph (4) of this definition, constitutes a different operating scenario.

(1) A description of the process, the specific process equipment used, and the range of operating conditions for the process.

(2) An identification of related process vents, their associated emissions episodes and durations, and calculations and engineering analyses to show the annual uncontrolled emissions of controlled substances from the process vent.

(3) The control or destruction units used, as applicable, including a description of operating and/or testing conditions for any associated destruction unit.

(4) The process vents (including those from other processes) that are simultaneously routed to the control or destruction unit(s).

(5) The applicable monitoring requirements and any parametric level that assures destruction or removal for all emissions routed to the control or destruction unit.

* * * * *

Plant means any process equipment (e.g., reactor, distillation column) used to convert raw materials or feedstock chemicals into controlled substances or use controlled substances in the production of other chemicals.

* * * * *

Process (for the purposes of § 82.25 only) means all equipment that collectively functions to engage in an activity listed in § 82.25(b)(2). A process may consist of one or more unit

operations. For the purposes of § 82.25, process includes any, all, or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to engage in an activity listed in § 82.25(b)(2). For a continuous process, cleaning operations may be considered part of the process at the discretion of the facility. For a batch process, cleaning operations are part of the process. Ancillary activities are not considered a process or part of any process under § 82.25. Ancillary activities include boilers and incinerators, chillers and refrigeration systems, and other equipment and activities that are not directly involved (i.e., they operate within a closed system and materials are not combined with process fluids) in an activity listed in § 82.25(b)(2).

Process agent means a controlled substance used to form the environment for a chemical reaction or inhibit an unintended chemical reaction (e.g., use as a solvent, catalyst, or stabilizer) where the controlled substance is not consumed in the reaction, but is removed or recycled back into the process and where no more than trace quantities remain in the final product. A feedstock, in contrast, is consumed during the reaction. The term process agent includes, but is not limited to: carbon tetrachloride used in the elimination of nitrogen trichloride in chlor-alkali production, carbon tetrachloride used in the recovery of chlorine by tail gas absorption from chlor-alkali production, CFC-11 used in the production of synthetic fiber sheet, bromochloromethane used in the bromination of a styrenic polymer, and CFC-113 used in the production of high modulus polyethylene fiber.

Process condenser means a condenser whose primary purpose is to recover material as an integral part of a process. All condensers recovering condensate from a process vent at or above the boiling point or all condensers in line prior to a vacuum source are considered process condensers. Typically, a primary condenser or condensers in series are considered to be integral to the process if they are capable of and normally used for the purpose of recovering chemicals for fuel value (i.e., net positive heating value), use, reuse or for sale for fuel value, use, or reuse.

Process vent means a vent from a process vessel or vents from multiple process vessels within a process that are manifolded together into a common header, through which a controlled substance-containing gas stream is, or has the potential to be, released to the atmosphere (or the point of entry into a

control device, if any). Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottoms receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Process vents do not include vents on storage tanks, wastewater emission sources, or pieces of equipment.

* * * * *

Typical batch means a batch process operated within a range of operating conditions that are documented in an operating scenario. Emissions from a typical batch are based on the operating conditions that result in representative emissions. The typical batch defines the uncontrolled emissions for each emission episode defined under the operating scenario.

Uncontrolled emissions of controlled substance means a gas stream containing a controlled substance which has exited the process (or process condenser or control condenser, where applicable), but which has not yet been introduced into a destruction unit to reduce the mass of controlled substance in the stream. If the emissions from the process are not routed to a destruction unit, uncontrolled emissions are those controlled substance emissions released to the atmosphere.

* * * * *

Unsafe-to-monitor means that monitoring personnel would be exposed to an immediate danger as a consequence of monitoring the piece of equipment. Examples of unsafe-to-monitor equipment include, but are not limited to, equipment under extreme pressure or heat.

* * * * *

■ 3. Amend § 82.13 by:

■ a. In paragraph (c), adding the words “or another format specified by EPA” after the words “Central Data Exchange”; and

■ b. Adding paragraph (ee).

The addition reads as follows:

§ 82.13 Recordkeeping and reporting requirements for class I controlled substances.

* * * * *

(ee) *Process agents*. Any entity that uses a class I controlled substance as a process agent must comply, in addition to the recordkeeping and reporting requirements in § 82.25, with the following recordkeeping and reporting requirements for each facility that uses a class I controlled substance as a process agent:

(1) *Reporting—one-time report*. By February 7, 2025, or within 120 days of the date that an entity first uses a class I controlled substance as a process

agent, whichever is later, any entity that uses a class I controlled substance as a process agent must submit to the Administrator a report containing the following information for each use of a class I controlled substance as a process agent:

(i) The name and address of each facility and plant, and each responsible person's name, email address, and phone number;

(ii) The name, purpose, and final product manufactured of each process agent application that uses a class I controlled substance;

(iii) The start-up date of each facility and the start-up date of each plant that uses a class I controlled substance as a process agent;

(iv) For each facility, the names and amounts of each product and byproduct manufactured in the process agent application during the previous control period, including amounts destroyed or used as a feedstock;

(v) For each facility, the total air, fugitive air, and stack point air emissions of class I controlled substances used as a process agent during the previous control period;

(vi) For each facility, a description of technologies currently being used and actions taken or currently under evaluation to minimize use or emissions of class I controlled substances used as process agents (including estimated emissions reductions associated with each); and

(vii) For each facility, a description that includes details of the percentages of class I controlled substances used as a process agent and:

(A) Retained within the process agent application;

(B) Consumed in the process agent application;

(C) Recovered after the process agent application;

(D) Emitted; and

(E) Entrained in the final product.

(2) *Annual reports.* Any entity that uses a class I controlled substance as a process agent must provide by February 14 of each year an annual report for the previous control period containing the following information for each use of the class I controlled substance as a process agent:

(i) For each facility, contact information including email address and phone number for a primary and alternate contact person;

(ii) For each facility, the name and amount of each class I controlled substance initially introduced into the process agent application for use as a process agent, specified independently for paragraphs (ee)(2)(ii)(A) through (G)

of this section by whether the class I controlled substance was:

(A) Obtained as virgin;

(B) Obtained as used;

(C) Produced by the entity;

(D) Purchased from a U.S. producer;

(E) Imported;

(F) Reclaimed by the entity from a different use; and

(G) Reclaimed by another entity;

(iii) For each facility, the name and amount of each class I controlled substance used as a process agent and reused or recycled for use by the entity for continued use in the same process agent application at the same facility;

(iv) For each facility, the name and amount of each class I controlled substance used as a process agent that was ultimately:

(A) Transformed;

(B) Reused or recycled for use in a different process agent application; or

(C) Destroyed by approved destruction technologies;

(v) For each facility, the total air, fugitive air, and stack point air emissions of each class I controlled substance used as a process agent;

(vi) For each facility, the names and amounts of each product and byproduct manufactured in the process agent application during the previous control period, including amounts destroyed or used as a feedstock;

(vii) For each facility, a description of emission reduction actions for class I controlled substances used as a process agent taken since the last one-time or annual report, planned, or currently under evaluation; and

(viii) For each entity, any process agent application changes anticipated to result in increases for the next annual report, as compared to the previous control period and the average of the three previous control periods, of the following magnitude must be specified in a report submitted to EPA at least 180 days prior to implementing the change:

(A) Greater than 20 percent of the amount of class I controlled substance initially introduced for use as a process agent; or

(B) At least one metric ton and 20 percent of the amount emitted during use as a process agent.

(3) *Recordkeeping.* Every entity who uses a class I controlled substance as a process agent during a control period must maintain the following records, as applicable:

(i) Dated records of the quantity of each class I controlled substance initially introduced at each facility into the process application for use as a process agent;

(ii) Dated records of the quantity of each class I controlled substance

produced at each facility for use as a process agent;

(iii) Records identifying the producer or importer of the class I controlled substance received at each facility for use as a process agent by the entity;

(iv) For each facility, copies of the invoices or receipts documenting the sale or other transfer of ownership of each class I controlled substance for use as a process agent to the entity;

(v) Dated records identifying the quantity of each product manufactured within each facility by using a class I controlled substance as a process agent;

(vi) For each facility, records of the date and the estimated quantity of any spill or release of each class I controlled substance used as a process agent that equals or exceeds 100 pounds;

(vii) For each facility, a description of the methodology used to measure and calculate emissions, and dated records of equipment parameters, measured data, supporting calculations, and other rationale used to validate reported emission quantities;

(viii) For each facility, dated records of the quantity of each class I controlled substance used as a process agent which is subsequently transformed or destroyed;

(ix) In the case where class I controlled substances used as a process agent were ultimately transformed by an entity other than the entity which last used the class I controlled substances as a process agent, a copy of the Internal Revenue Service Certificate showing that the purchaser or recipient of the controlled substance, in the United States or in another country that is a Party, certifies the intent to transform the controlled substance, or sell the controlled substance for transformation; and

(x) In the case where class I controlled substances used as a process agent were ultimately destroyed by an entity other than the entity which last used the class I controlled substances as a process agent, a copy of the destruction verification (as in paragraph (k) of this section), showing that the purchaser or recipient of a controlled substance, in the United States or in another country that is a Party, certifies the intent to destroy the controlled substance, or sell the controlled substance for destruction.

(4) *Request for extension.* Any entity that uses a class I controlled substance as a process agent may request an extension to comply with paragraph (ee)(1) of this section.

(i) This request must include the following information:

(A) Name of the facility submitting the request, contact information for a

person at the facility, and the address of the facility;

(B) An explanation of the reasons that an extension is necessary and the timeline that would be practicable; and

(C) Supporting documentation of the circumstances.

(ii) The Administrator will review the request and, within five working days of receiving a complete request, provide notification of whether the request is granted and when the report is due.

(5) *Notification that use has ceased.* Reports are no longer required for process agent use starting in the year after an entity notifies the Administrator that they have permanently ceased use of all class I controlled substances as a process agent, but the entity must continue to comply with all applicable recordkeeping requirements.

§ 82.14 [Amended]

■ 4. Amend § 82.14, in paragraph (a), by adding the words “or another format specified by EPA” after the words “Central Data Exchange.”

■ 5. Amend § 82.24 by:

■ a. In paragraph (a)(1), adding the words “or another format specified by EPA” after the words “Central Data Exchange”; and

■ b. Adding paragraph (g).

The addition reads as follows:

§ 82.24 Recordkeeping and reporting requirements for class II controlled substances.

* * * * *

(g) *Process agents.* Any entity that uses a class II controlled substance as a process agent must comply, in addition to the recordkeeping and reporting requirements in § 82.25, with the following recordkeeping and reporting requirements for each facility that uses a class II controlled substance as a process agent:

(1) *Reporting—one-time report.* By February 7, 2025, or within 120 days of the date that an entity first uses a class II controlled substance as a process agent, whichever is later, any entity that uses a class II controlled substance as a process agent must submit to the Administrator a report containing the following information for each use of a class II controlled substance as a process agent:

(i) The name and address of each facility and plant, and each responsible person's name, email address, and phone number;

(ii) The name, purpose, and final product manufactured of each process agent application that uses a class II controlled substance;

(iii) The start-up date of each facility and the start-up date of each plant that

uses a class II controlled substance as a process agent;

(iv) For each facility, the names and amounts of each product and byproduct manufactured in the process agent application during the previous control period, including amounts destroyed or used as a feedstock;

(v) For each facility, the total air, fugitive air, and stack point air emissions of class II controlled substances used as a process agent during the previous control period;

(vi) For each facility, a description of technologies currently being used and actions taken or currently under evaluation to minimize use or emissions of class II controlled substances used as process agents (including estimated emissions reductions associated with each); and

(vii) For each facility, a description that includes details of the percentages of class II controlled substances used as a process agent and:

(A) Retained within the process agent application;

(B) Consumed in the process agent application;

(C) Recovered after the process agent application;

(D) Emitted; and

(E) Entrained in the final product.

(2) *Annual reports.* Any entity that uses a class II controlled substance as a process agent must provide by February 14 of each year an annual report for the previous control period containing the following information for each use of the class II controlled substance as a process agent:

(i) For each facility, contact information including email address and phone number for a primary and alternate contact person;

(ii) For each facility, the name and amount of each class II controlled substance initially introduced into the process agent application for use as a process agent, specified independently for paragraphs (g)(2)(ii)(A) through (G) of this section by whether the class II controlled substance was:

(A) Obtained as virgin;

(B) Obtained as used;

(C) Produced by the entity;

(D) Purchased from a U.S. producer;

(E) Imported;

(F) Reclaimed by the entity from a different use; and

(G) Reclaimed by another entity;

(iii) For each facility, the name and amount of each class II controlled substance used as a process agent and reused or recycled for use by the entity for continued use in the same process agent application at the same facility;

(iv) For each facility, the name and amount of each class II controlled

substance used as a process agent that was ultimately:

(A) Transformed;

(B) Reused or recycled for use in a different process agent application; or

(C) Destroyed by approved destruction technologies;

(v) For each facility, the total air, fugitive air, and stack point air emissions of each class II controlled substance used as a process agent;

(vi) For each facility, the names and amounts of each product and byproduct manufactured in the process agent application during the previous control period, including amounts destroyed or used as a feedstock;

(vii) For each facility, a description of emission reduction actions for class II controlled substances used as a process agent taken since the last one-time or annual report, planned, or currently under evaluation; and

(viii) For each entity, any process agent application changes anticipated to result in increases for the next annual report, as compared to the previous control period and the average of the three previous control periods, of the following magnitude must be specified in a report submitted to EPA at least 180 days prior to implementing the change:

(A) Greater than 20 percent of the amount of class II controlled substance initially introduced for use as a process agent; or

(B) At least one metric ton and 20 percent of the amount emitted during use as a process agent.

(3) *Recordkeeping.* Every entity who uses a class II controlled substance as a process agent during a control period must maintain the following records, as applicable:

(i) Dated records of the quantity of each class II controlled substance initially introduced at each facility into the process application for use as a process agent;

(ii) Dated records of the quantity of each class II controlled substance produced at each facility for use as a process agent;

(iii) Records identifying the producer or importer of the class II controlled substance received at each facility for use as a process agent by the entity;

(iv) For each facility, copies of the invoices or receipts documenting the sale or other transfer of ownership of each class II controlled substance for use as a process agent to the entity;

(v) Dated records identifying the quantity of each product manufactured within each facility by using a class II controlled substance as a process agent;

(vi) For each facility, records of the date and the estimated quantity of any spill or release of each class II

controlled substance used as a process agent that equals or exceeds 100 pounds;

(vii) For each facility, a description of the methodology used to measure and calculate emissions, and dated records of equipment parameters, measured data, supporting calculations, and other rationale used to validate reported emission quantities;

(viii) For each facility, dated records of the quantity of each class II controlled substance used as a process agent which is subsequently transformed or destroyed;

(ix) In the case where class II controlled substances used as a process agent were ultimately transformed by an entity other than the entity which last used the class II controlled substances as a process agent, a copy of the entity's transformation verification as provided under paragraph (e)(3) of this section; and

(x) In the case where class II controlled substances used as a process agent were ultimately destroyed by an entity other than the entity which last used the class II controlled substances as a process agent, a copy of the entity's destruction verification, as provided under paragraph (e)(5) of this section.

(4) *Request for extension.* Any entity that uses a class II controlled substance as a process agent may request an extension to comply with paragraph (g)(1) of this section.

(i) This request must include the following information:

(A) Name of the facility submitting the request, contact information for a person at the facility, and the address of the facility;

(B) An explanation of the reasons that an extension is necessary and the timeline that would be practicable; and

(C) Supporting documentation of the circumstances.

(ii) The Administrator will review the request and, within five working days of receiving a complete request, provide notification of whether the request is granted and when the report is due.

(5) *Notification that use has ceased.* Reports are no longer required for process agent use starting in the year after an entity notifies the Administrator that they have permanently ceased use of all class II controlled substances as a process agent, but the entity must continue to comply with all applicable recordkeeping requirements.

■ 6. Add § 82.25 to read as follows:

§ 82.25 Emissions of controlled substances from industrial sources.

(a) *Source applicability.* The requirements specified in this section apply to every entity which engages in any of the following activities:

(1) Use of a controlled substance as a process agent.

(2) [Reserved]

(b) *Emissions of controlled substances to report.* Every entity that engages in any activity listed in paragraph (a) of this section must report, for each applicable facility, emissions of the controlled substances in paragraph (b)(1) of this section from the processes listed in paragraph (b)(2) of this section.

(1) *Emissions of controlled substances.* For purposes of reporting emissions under this section, the term “controlled substance” applies to the following controlled substances:

(i) Each controlled substance used as a process agent.

(ii) [Reserved]

(2) *Processes.* For purposes of this section, the term “process” applies to the following activities:

(i) Each activity listed in paragraph (a) of this section;

(ii) Each separation process for the reuse or recycling of the controlled substance;

(iii) Each transformation process of the controlled substance, where the controlled substance is produced at the facility and used in processes resulting in its transformation at the same facility;

(iv) Each transformation process of the controlled substance at the facility, where one or more of the controlled substances transformed at the facility is produced at another facility; and

(v) Each destruction process of the controlled substance.

(c) *Calculating emissions for controlled substances.* For every activity listed in paragraph (a) of this section, each entity must calculate emissions of the controlled substances from each process using the emission factor, emission calculation factor, or mass balance method specified in paragraphs (c)(1) through (4) of this section, as appropriate. The mass balance method may only be used for batch operations without on-site production or transformation of controlled substances. For destruction processes that destroy controlled substances, the entity must calculate emissions using the procedures in paragraph (c)(4) of this section.

(1) *Emission factor and emission calculation factor methods.* To use the method in this paragraph (c)(1) for batch processes, each entity must use the methods in either paragraph (c)(1)(iii) (Emission Factor approach) or (iv) (Emission Calculation Factor approach) of this section. To use the method in this paragraph (c)(1) for continuous processes, the entity must first make a preliminary estimate of the emissions from each individual continuous

process vent under paragraph (c)(1)(i) of this section. If the entity's continuous process operates under different conditions as part of normal operations, that entity must also define the different operating scenarios and make a preliminary estimate of the emissions from the vent for each operating scenario. Then, compare the preliminary estimate for each continuous process vent (summed across operating scenarios) to the criteria in paragraph (c)(1)(ii) of this section to determine whether the process vent meets the criteria for using the emission factor method described in paragraph (c)(1)(iii) of this section or whether the process vent meets the criteria for using the emission calculation factor method described in paragraph (c)(1)(iv) of this section. For continuous process vents that meet the criteria for using the emission factor method described in paragraph (c)(1)(iii) of this section and that have more than one operating scenario, compare the preliminary estimate for each operating scenario to the criteria in paragraph (c)(1)(iii)(B) of this section to determine whether an emission factor must be developed for that operating scenario.

(i) *Preliminary estimate of emissions by process vent.* Each entity must estimate the annual emissions of the controlled substance for each process vent within each operating scenario of a continuous process using the approaches specified in paragraph (c)(1)(i)(A) or (B) of this section, accounting for any destruction as specified in paragraph (c)(1)(i)(C) of this section. The entity must determine emissions of controlled substances by process vent by using measurements, by using calculations based on chemical engineering principles and chemical property data, or by conducting an engineering assessment. The entity may use previously conducted measurements, calculations, or assessments if they represent current process operating conditions or process operating conditions that would result in higher controlled substance emissions than the current operating conditions and if they were performed in accordance with paragraph (c)(1)(i)(A), (B), or (C) of this section, as applicable. The entity must document all data, assumptions, and procedures used in the calculations or engineering assessment and keep a record of the emissions determination as required by paragraph (f)(1) of this section.

(A) *Engineering calculations.* For process vent emission calculations, each entity may use any of paragraph (c)(1)(i)(A)(1), (2), or (3) of this section.

(1) U.S. Environmental Protection Agency, Emission Inventory Improvement Program, Volume II: Chapter 16, Methods for Estimating Air Emissions from Chemical Manufacturing Facilities, August 2007, Final (incorporated by reference, see § 82.27).

(2) Each entity may determine the controlled substance emissions from any process vent within the process using the procedures specified in § 63.1257(d)(2)(i) and (d)(3)(i)(B) of this chapter, except as specified in paragraphs (c)(1)(i)(A)(2)(i) through (iv) of this section. For the purposes of this section, use of the term “HAP” in § 63.1257(d)(2)(i) and (d)(3)(i)(B) of this chapter means “controlled substance.”

(i) To calculate emissions caused by the heating of a vessel without a process condenser to a temperature lower than the boiling point, each entity must use the procedures in § 63.1257(d)(2)(i)(C)(3) of this chapter.

(ii) To calculate emissions from depressurization of a vessel without a process condenser, each entity must use the procedures in § 63.1257(d)(2)(i)(D)(10) of this chapter.

(iii) To calculate emissions from vacuum systems, the terms used in equation 33 to § 63.1257(d)(2)(i)(E) of this chapter are defined as follows. P_{system} means the absolute pressure of the receiving vessel. P_i means the partial pressure of the controlled substance determined at the exit temperature and exit pressure conditions of the condenser or at the conditions of the dedicated receiver. P_j means the partial pressure of condensables (including controlled substances) determined at the exit temperature and exit pressure conditions of the condenser or at the conditions of the dedicated receiver. $MW_{\text{controlled substance}}$ means the molecular weight of the controlled substance determined at the exit temperature and exit pressure conditions of the condenser or at the conditions of the dedicated receiver.

(iv) To calculate emissions when a vessel is equipped with a process condenser or a control condenser, each entity must use the procedures in § 63.1257(d)(3)(i)(B) of this chapter, except as follows. Each entity must determine the flow rate of gas (or volume of gas), partial pressures of condensables, temperature (T), and controlled substance molecular weight ($MW_{\text{controlled substance}}$) at the exit temperature and exit pressure conditions of the condenser or at the conditions of the dedicated receiver. Each entity must assume that all of the components contained in the condenser exit vent stream are in equilibrium with

the same components in the exit condensate stream (except for noncondensables). Each entity must perform a material balance for each component, if the condensate receiver composition is not known. For the emissions from purging, the term for time, t , must be used in equation 12 to § 63.1257(d)(2)(i)(B) of this chapter. Emissions from empty vessel purging must be calculated using equation 36 to § 63.1257(d)(2)(i)(H) of this chapter and the exit temperature and exit pressure conditions of the condenser or the conditions of the dedicated receiver.

(3) Commercial software products that follow chemical engineering principles (e.g., including the calculation methodologies in paragraphs (c)(1)(i)(A)(1) and (2) of this section).

(B) *Engineering assessments.* For process vent emissions determinations, each entity may conduct an engineering assessment to calculate uncontrolled emissions. An engineering assessment includes, but is not limited to, the following:

(1) Previous test results, provided the tests are representative of current operating practices of the process.

(2) Bench-scale or pilot-scale test data representative of the process operating conditions.

(3) Maximum flow rate, controlled substance emission rate, concentration, or other relevant parameters specified or implied within a permit limit applicable to the process vent.

(4) Design analysis based on chemical engineering principles, measurable process parameters, or physical or chemical laws or properties.

(C) *Impact of destruction for the preliminary estimate.* If the process vent is vented to a destruction unit, each entity may reflect the impact of the destruction unit on emissions. In the emissions estimate, account for the following:

(1) The demonstrated destruction efficiencies of the device for the controlled substance in the vent stream for periods when the destruction device is in use.

(2) Any periods when the process vent is not vented to the destruction unit.

(D) *Use of typical recent values.* In the calculations in paragraphs (c)(1)(i)(A) through (C) of this section, the values used for the expected process activity and for the expected fraction of that activity, whose emissions will be vented to the properly functioning destruction unit, must be based on either typical recent values for the process or values that overestimate emissions from the process, unless there is a compelling reason to adopt a different value (e.g.,

installation of a destruction unit for a previously uncontrolled process). If there is such a reason, it must be documented in the monitoring plan.

(ii) *Method selection for continuous process vents.* (A) Based on the calculations under paragraph (c)(1)(i) of this section, as well as any subsequent measurements and calculations under this section, rank the process vents based on controlled substance emissions, upstream of any destruction unit, summed across all operating scenarios, from largest to smallest estimated annual emissions of controlled substances. The continuous process vents that comprise the top quartile of estimated annual emissions of controlled substances must use the method in paragraph (c)(1)(iii) of this section (Emission Factor approach). The process vent emissions will be based on the past 3 years for the ranking analysis.

(B) The remaining continuous process vents that comprise the bottom three quartiles of estimated annual emissions of controlled substances may use either the emission factor method specified in paragraph (c)(1)(iii) of this section (Emission Factor approach) or a method specified in paragraph (c)(1)(iv) of this section (Emission Calculation Factor approach).

(1) Each entity must conduct emission testing for process-vent-specific emission factor development upstream of the destruction unit.

(2) The emission testing for process-vent-specific emission factor development may be conducted on the outlet side of a wet scrubber in place for acid gas reduction, if there is no appreciable reduction in the controlled substance by the wet scrubber.

(iii) *Process-vent-specific emission factor method.* For each process vent, each entity must conduct an emission test according to the procedures in paragraph (d) of this section and measure the process activity, such as the feed rate, production rate, or other process activity rate, during the test as described in this paragraph (c)(1)(iii). All emissions test data and procedures used in developing emission factors must be documented according to paragraph (f) of this section. If more than one operating scenario applies to the process that contains the subject process vent, each entity must use the method in either paragraph (c)(1)(iii)(A) or (B) of this section.

(A) Conduct a separate emissions test for operation under each operating scenario.

(B) Conduct an emissions test for the operating scenario that is expected to have the largest emissions of controlled substances (considering both activity

levels and emission calculation factors) on an annual basis. Also conduct an emissions test for each additional operating scenario for which the emission calculation factor differs by 15 percent or more from the emission calculation factor of the operating scenario that is expected to have the largest emissions (or of another operating scenario for which emission testing is performed), unless the difference between the operating scenarios is solely due to the application of a

destruction unit to emissions under one of the operating scenarios. For any other operating scenarios, adjust the process-vent specific emission factor developed for the operating scenario that is expected to have the largest emissions (or for another operating scenario for which emission testing is performed) using the approach in paragraph (c)(1)(iii)(G) of this section.

(C) Each entity must measure the process activity, such as the process feed rate, process production rate, or other process activity rate, as applicable,

during the emissions test and calculate the rate for the test period, in kg (or another appropriate metric) per hour.

(D) For continuous processes, each entity must calculate the hourly emission rate of each controlled substance using equation 1 to this paragraph (c)(1)(iii)(D) and determine the hourly emission rate of each controlled substance per process vent (and per operating scenario, as applicable) for the test run.

Equation 1 to Paragraph (c)(1)(iii)(D)

$$E_{ContPV} = \frac{C_{PV}}{10^6} * MW * Q_{PV} * \frac{1}{SV} * \frac{1}{10^3} * \frac{60}{1}$$

Where:

E_{ContPV} = Mass of controlled substance p emitted from process vent v from process i, operating scenario j, during the emission test during test run r (kg/hr).

C_{PV} = Concentration of controlled substance p during test run r of the emission test (ppmv).

MW = Molecular weight of controlled substance p (g/g-mole).

Q_{PV} = Flow rate of the process vent stream during test run r of the emission test (m³/min).

SV = Standard molar volume of gas (0.0240 m³/g-mole at 68 °F and 1 atm).

1/10³ = Conversion factor (1 kilogram/1,000 grams).

60/1 = Conversion factor (60 minutes/1 hour).

(E) Each entity must calculate a site-specific, process-vent-specific emission factor for each controlled substance for each process vent and each operating scenario, in kg of controlled substance per process activity rate (e.g., kg of feed or production), as applicable, using equation 2 to this paragraph (c)(1)(iii)(E). For continuous processes, divide the hourly controlled substance emission rate during the test by the hourly process activity rate during the test runs.

Equation 2 to Paragraph (c)(1)(iii)(E)

$$EF_{PV} = \frac{\sum_1^r \left(\frac{E_{PV}}{Activity_{EmissionTest}} \right)}{r}$$

Where:

EF_{PV} = Emission factor for controlled substance p emitted from process vent v during process i, operating scenario j (e.g., kg emitted/kg activity).

E_{PV} = Mass of controlled substance p emitted from process vent v from process i, operating scenario j, during the emission test during test run r, for either continuous or batch (kg emitted/hr for continuous, kg emitted/batch for batch).

$Activity_{EmissionTest}$ = Process feed, process production, or other process activity rate for process i, operating scenario j, during the emission test during test run r (e.g., kg product/hr).

r = Number of test runs performed during the emission test.

(F) If emissions testing is conducted upstream of the destruction unit, apply the destruction efficiencies of the device that have been demonstrated for the controlled substance in the vent stream to the controlled substance emissions for the process vent (and operating scenario, as applicable), using equation 3 to this paragraph (c)(1)(iii)(F). Each entity may apply the destruction efficiency only to the portion of the process activity during which emissions are vented to the properly functioning destruction unit (i.e., controlled).

Equation 3 to Paragraph (c)(1)(iii)(F)

$$E_{PV} = EF_{PV-U} * (Activity_u + Activity_c * (1 - DE))$$

Where:

E_{PV} = Mass of controlled substance p emitted from process vent v from process i, operating scenario j, for the year, considering destruction efficiency (kg).

EF_{PV-U} = Emission factor (uncontrolled) for controlled substance p emitted from process vent v during process i, operating scenario j (kg emitted/kg product).

$Activity_u$ = Total process feed, process production, or other process activity for process i, operating scenario j, during the year for which the process vent is not vented to the properly functioning destruction unit (e.g., kg product).

$Activity_c$ = Total process feed, process production, or other process activity for process i, operating scenario j, during the year for which the process vent is vented to the properly functioning destruction unit (e.g., kg product).

DE = Demonstrated destruction efficiency of the destruction unit (weight fraction).

(G) For process vents from processes with multiple operating scenarios, use

equation 4 to this paragraph (c)(1)(iii)(G) to develop an adjusted process-vent-specific emission factor for each operating scenario whose emission calculation factor differs by less than 15 percent from the emission calculation factor of the operating scenario that is expected to have the largest emissions (or of another operating scenario for which emission testing is performed).

Equation 4 to Paragraph (c)(1)(iii)(G)

$$EF_{PVadj} = \frac{ECF_{UT}}{ECF_T} = * EF_{PV}$$

Where:

EF_{PVadj} = Adjusted process-vent-specific emission factor for an untested operating scenario.

ECF_{UT} = Emission calculation factor for the untested operating scenario developed under paragraph (c)(4) of this section.

ECF_T = Emission calculation for the tested operating scenario developed under paragraph (c)(4) of this section.

EF_{PV} = Process vent specific emission factor for the tested operating scenario.

(H) Sum the emissions of each controlled substance from all process vents in each operating scenario and all operating scenarios in the process for the year to estimate the total process vent emissions of each controlled substance from the process, using equation 5 to this paragraph (c)(1)(iii)(H).

Equation 5 to Paragraph (c)(1)(iii)(H)

$$E_{Ppi} = \sum_1^o \sum_1^v E_{PV}$$

Where:

E_{Ppi} = Mass of controlled substance p emitted from process vents for process i for the year (kg).

E_{PV} = Mass of controlled substance p emitted from process vent v from process i,

operating scenario j, for the year, considering destruction efficiency (kg).
 v = Number of process vents in process i, operating scenario j.
 o = Number of operating scenarios for process i.

(iv) *Process-vent-specific emission calculation factor method.* For each process vent within an operating scenario, determine controlled substances emissions by calculations and determine the process activity rate, such as the feed rate, production rate, or other process activity rate, associated with the emission rate.

(A) Each entity must calculate uncontrolled emissions of controlled substances by individual process vent, E_{PV} , by using measurements, by using calculations based on chemical engineering principles and chemical property data, or by conducting an engineering assessment. Use the procedures in paragraph (c)(1)(i)(A) or (B) of this section, except paragraph (c)(1)(i)(B)(3) of this section. The procedures in paragraphs (c)(1)(i)(A) and (B) of this section may be applied either to batch process vents or to continuous process vents. The uncontrolled emissions must be based on a typical batch or production rate under a defined operating scenario. The process activity rate associated with the uncontrolled emissions must be determined. The methods, data, and assumptions used to estimate emissions for each operating scenario must be selected to yield a best estimate (expected value) of emissions rather than an over- or underestimate of emissions for that operating scenario. All data, assumptions, and procedures used in the calculations or engineering assessment must be documented according to paragraph (f) of this section.

(B) Each entity must calculate a site-specific, process-vent-specific emission calculation factor for each process vent each operating scenario, and each controlled substance, in kg of controlled substance per activity rate (e.g., kg of feed or production) as applicable, using equation 6 to this paragraph (c)(1)(iv)(B).

Equation 6 to Paragraph (c)(1)(iv)(B)

$$ECF_{PV} = \frac{E_{PV}}{Activity_{Representative}}$$

Where:

ECF_{PV} = Emission calculation factor for controlled substance p emitted from process vent v during process i, operating scenario j (e.g., kg emitted/kg product).

E_{PV} = Average mass of controlled substance p emitted, based on calculations, from

process vent v from process i, operating scenario j, during the period or batch for which emissions were calculated, for either continuous or batch (kg emitted/hr for continuous, kg emitted/batch for batch).

Activity Representative = Process feed, process production, or other process activity rate corresponding to average mass of emissions based on calculations (e.g., kg product/hr for continuous, kg product/batch for batch).

(C) Each entity must calculate emissions of each controlled substance for the process vent (and for each operating scenario, as applicable) for the year by multiplying the process-vent-specific emission calculation factor by the total process activity, as applicable, for the year, using equation 7 to this paragraph (c)(1)(iv)(C).

Equation 7 to Paragraph (c)(1)(iv)(C)

$$E_{PV} = ECF_{PV} * Activity$$

Where:

E_{PV} = Mass of controlled substance p emitted from process vent v from process i, operating scenario j, for the year (kg).

ECF_{PV} = Emission calculation factor for controlled substance p emitted from process vent v during process i, operating scenario j (kg emitted/activity) (e.g., kg emitted/kg product).

Activity = Process feed, process production, or other process activity for process i, operating scenario j, during the year.

(D) If the process vent is vented to a destruction unit, apply the demonstrated destruction efficiency of the device to the controlled substance emissions for the process vent (and operating scenario, as applicable), using equation 8 to this paragraph (c)(1)(iv)(D). Apply the destruction efficiency only to the portion of the process activity that is vented to the properly functioning destruction unit (i.e., controlled).

Equation 8 to Paragraph (c)(1)(iv)(D)

$$E_{PV} = ECF_{PV} * (Activity_u + Activity_c * (1 - DE))$$

Where:

E_{PV} = Mass of controlled substance p emitted from process vent v from process i, operating scenario j, for the year considering destruction efficiency (kg).

ECF_{PV} = Emission calculation factor for controlled substance p emitted from process vent v during process i, operating scenario j (e.g., kg emitted/kg product).

Activity_U = Total process feed, process production, or other process activity for process i, operating scenario j, during the year for which the process vent is not vented to the properly functioning destruction unit (e.g., kg product).

Activity_C = Total process feed, process production, or other process activity for process i, operating scenario j, during the year for which the process vent is vented

to the properly functioning destruction unit (e.g., kg product).

DE = Demonstrated destruction efficiency of the destruction unit (weight fraction).

(E) Sum the emissions of each controlled substance from all process vents in each operating scenario and all operating scenarios in the process for the year to estimate the total process vent emissions of each controlled substance from the process, using equation 9 to this paragraph (c)(1)(iv)(E).

Equation 9 to Paragraph (c)(1)(iv)(E)

$$E_{Ppi} = \sum_1^o \sum_1^v E_{PV}$$

Where:

E_{Ppi} = Mass of controlled substance p emitted from process vents for process i for the year (kg).

E_{PV} = Mass of controlled substance p emitted from process vent v from process i, operating scenario j, for the year, considering destruction efficiency (kg).

v = Number of process vents in process i, operating scenario j.

o = Number of operating scenarios in process i.

(2) *Calculate emissions for equipment leaks (EL).* If activity is covered under paragraph (c)(1) of this section, each entity must calculate the emissions from pieces of equipment associated with processes covered under this section. If conducting monitoring of equipment in controlled substance service, monitoring must be conducted for those in light liquid and in gas and vapor service. If conducting monitoring of equipment in controlled substance service, the entity may exclude from monitoring each piece of equipment that is difficult-to-monitor, that is unsafe-to-monitor, that is insulated, or that is in heavy liquid service; the entity may exclude from monitoring each pump with dual mechanical seals, agitator with dual mechanical seals, pump with no external shaft, agitator with no external shaft; the entity may exclude from monitoring each pressure relief device in gas and vapor service with upstream rupture disk, each sampling connection system with closed-loop or closed-purge systems, and any pieces of equipment where leaks are routed through a closed vent system to a destruction unit. The entity must estimate emissions using another approach for those pieces of equipment excluded from monitoring. Equipment that is in controlled substance service for less than 300 hr/yr, equipment that is in vacuum service, pressure relief devices that are in light liquid service, and instrumentation systems are exempted from the requirements in this paragraph (c)(2).

(i) The emissions from equipment leaks must be calculated using any of the procedures in paragraphs (c)(2)(i)(A), (B), (C), or (D) of this section.

(A) *Use of Average Emission Factor Approach in EPA protocol for equipment leak emission estimates.* The emissions from equipment leaks may be calculated using the default Average Emission Factor Approach in EPA-453/R-95-017 (incorporated by reference, see § 82.27).

(B) *Use of Other Approaches in EPA protocol for equipment leak emission estimates in conjunction with EPA Method 21.* The emissions from equipment leaks may be calculated using one of the following methods in EPA-453/R-95-017 (incorporated by reference, see § 82.27): The Screening Ranges Approach; the EPA Correlation Approach; or the Unit-Specific Correlation Approach. If it is determined that EPA Method 21 in appendix A-7 to 40 CFR part 60 is appropriate for monitoring a controlled substance, and if the instrument is calibrated with a compound different from one or more of the controlled substances or surrogates to be measured, each entity must develop response factors for each controlled substance or for each surrogate to be measured using EPA Method 21. For each controlled substance or surrogate measured, the response factor must be less than 10. The response factor is the ratio of the known concentration of a controlled substance or surrogate to the observed meter reading when measured using an instrument calibrated with the reference compound.

(C) *Use of Other Approaches in EPA protocol for equipment leak emission estimates in conjunction with site-specific leak monitoring methods.* The emissions from equipment leaks may be calculated using one of the following methods in EPA-453/R-95-017 (incorporated by reference, see § 82.27): The Screening Ranges Approach; the EPA Correlation Approach; or the Unit-Specific Correlation Approach. Each entity may develop a site-specific leak monitoring method appropriate for monitoring controlled substances or surrogates to use along with these three approaches. The site-specific leak monitoring method must meet the requirements in paragraph (d)(5)(i) of this section.

(D) *Use of site-specific leak monitoring methods.* The emissions from equipment leaks may be calculated using a site-specific leak monitoring method. The site-specific leak monitoring method must meet the

requirements in paragraph (d)(5)(i) of this section.

(ii) Each entity must collect information on the number of each type of equipment, the service of each piece of equipment (gas, light liquid, heavy liquid), the concentration of each controlled substance in the stream, and the time period each piece of equipment was in service (e.g., hours per year). Depending on which approach followed, the entity may be required to collect information for equipment on the associated screening data concentrations for greater than or equal to 10,000 ppmv and associated screening data concentrations for less than 10,000 ppmv; associated actual screening data concentrations; or associated screening data and leak rate data (i.e., bagging) used to develop a unit-specific correlation.

(iii) Calculate and sum the emissions of each controlled substance in kilograms per year for equipment pieces for each process, $E_{EL,p}$, annually. Each entity must include and estimate emissions for types of equipment that are excluded from monitoring, including difficult-to-monitor, unsafe-to-monitor and insulated pieces of equipment, pieces of equipment in heavy liquid service, pumps with dual mechanical seals, agitators with dual mechanical seals, pumps with no external shaft, agitators with no external shaft, pressure relief devices in gas and vapor service with upstream rupture disk, sampling connection systems with closed-loop or closed purge systems, and pieces of equipment where leaks are routed through a closed vent system to a destruction unit.

(3) *Calculate total controlled substance emissions for each process and for production or transformation processes at the facility.* (i) Estimate annually the total mass of each controlled substance emitted from each process, including emissions from process vents in paragraphs (c)(1)(iii) and (iv) of this section, as appropriate, and from equipment leaks in paragraph (c)(2) of this section, using equation 10 to this paragraph (c)(3)(i).

Equation 10 to Paragraph (c)(3)(i)

$$E_i = E_{Ppi} + E_{ELpi}$$

Where:

E_i = Total mass of each controlled substance p emitted from process i, annual basis (kg/year).

E_{Ppi} = Mass of controlled substance p emitted from all process vents and all operating scenarios in process i, annually (kg/year, calculated in equation 5 or 9 to this section, as appropriate).

E_{ELpi} = Mass of controlled substance p emitted from equipment leaks for pieces

of equipment for process i, annually (kg/year, calculated in paragraph (c)(2)(iii) of this section).

(ii) Estimate annually the total mass of each controlled substance emitted at the facility from each applicable process listed in paragraph (b)(2) of this section using equation 11 to this paragraph (c)(3)(ii). Develop separate totals for each applicable process listed in paragraph (b)(2) of this section.

Equation 11 to Paragraph (c)(3)(ii)

$$E = \sum_{i=1}^z E_i$$

Where:

E = Total mass of each controlled substance p emitted from all processes listed in paragraphs (b)(2)(i) through (iv) of this section, as appropriate (kilograms).

E_i = Total mass of each controlled substance p emitted from each process listed in paragraphs (b)(2)(i) through (iv) of this section, annual basis (kg/year, calculated in equation 10 to paragraph (c)(3)(i) of this section).

z = Total number of processes listed in paragraphs (b)(2)(i) through (iv) of this section, as appropriate.

(4) *Mass balance method.* Before using the mass balance approach to estimate your controlled substance emissions from a process, you must ensure that the process and the equipment and methods used to measure the process meet either the error limits described in this paragraph (c)(4) and calculated under paragraph (c)(4)(i) of this section or the requirements specified in paragraph (d)(4)(viii) of this section. If you choose to calculate the error limits, you must estimate the absolute and relative errors associated with using the mass balance approach on that process using equations 12 through 15 to this section in conjunction with equations 16 through 21 to this section. You may use the mass-balance approach to estimate emissions from the process if this calculation results in an absolute error of less than or equal to one metric ton of controlled substance per year or a relative error of less than or equal to 10 percent of the estimated controlled substance emissions. If you do not meet either of the error limits or the requirements of paragraph (d)(4)(viii) of this section, you must use the emission factor approach detailed in paragraphs (c)(1) through (3) of this section to estimate emissions from the process.

(i) To perform the calculation, you must first calculate the absolute and relative errors associated with the quantities calculated using either equations 18 through 21 to this section

or equation 28 to paragraph (c)(4)(xv) of this section. Alternatively, you may estimate these errors based on the variability of previous process measurements (e.g., the variability of measurements of stream concentrations), provided these measurements are representative of the current process and current measurement devices and techniques. Once errors have been calculated for the quantities in these equations, those errors must be used to calculate the errors in equations 16 and 17 to this section. You may omit the errors associated with equations 22 through 24 to this section.

(A) Where the measured quantity is a mass, the error in the mass must be equated to the accuracy or precision (whichever is larger) of the flowmeter, scale, or combination of volumetric and density measurements at the flow rate or mass measured.

(B) Where the measured quantity is a concentration of a stream component, the error of the concentration must be equated to the accuracy or precision (whichever is larger) with which you estimate the mean concentration of that stream component, accounting for the variability of the process, the frequency of the measurements, and the accuracy or precision (whichever is larger) of the analytical technique used to measure the concentration at the concentration measured. If the variability of process measurements is used to estimate the error, this variability shall be assumed to account both for the variability of the process and the precision of the analytical technique. Use standard statistical techniques such as the student's *t* distribution to estimate the error of the mean of the concentration measurements as a function of process variability and frequency of measurement.

(C) Equation 12 to this paragraph (c)(4)(i)(C) provides the general formula for calculating the absolute errors of sums and differences where the sum, *S*, is the summation of variables measured, *a*, *b*, *c*, etc. (e.g., *S* = *a* + *b* + *c*).

Equation 12 to Paragraph (c)(4)(i)(C)

$$e_{SA} = [(a * e_a)^2 + (b * e_b)^2 + (c * e_c)^2]^{1/2}$$

Where:

*e*_{SA} = Absolute error of the sum, expressed as one half of a 95 percent confidence interval.

*e*_a = Relative error of *a*, expressed as one half of a 95 percent confidence interval.

*e*_b = Relative error of *b*, expressed as one half of a 95 percent confidence interval.

*e*_c = Relative error of *c*, expressed as one half of a 95 percent confidence interval.

(D) Equation 13 to this paragraph (c)(4)(i)(D) provides the general formula

for calculating the relative errors of sums and differences.

Equation 13 to Paragraph (c)(4)(i)(D)

$$e_{SR} = \frac{e_{SA}}{(a + b + c)}$$

Where:

*e*_{SR} = Relative error of the sum, expressed as one half of a 95 percent confidence interval.

*e*_{SA} = Absolute error of the sum, expressed as one half of a 95 percent confidence interval.

a+*b*+*c* = Sum of the variables measured.

(E) Equation 14 to this paragraph (c)(4)(i)(E) provides the general formula for calculating the absolute errors of products (e.g., flow rates of controlled substances calculated as the product of the flow rate of the stream and the concentration of the controlled substance in the stream), where the product, *P*, is the result of multiplying the variables measured, *a*, *b*, *c*, etc. (e.g., *P* = *a***b***c*).

Equation 14 to Paragraph (c)(4)(i)(E)

$$e_{PA} = (a * b * c)(e_a^2 + e_b^2 + e_c^2)^{1/2}$$

Where:

*e*_{PA} = Absolute error of the product, expressed as one half of a 95 percent confidence interval.

*e*_a = Relative error of *a*, expressed as one half of a 95 percent confidence interval.

*e*_b = Relative error of *b*, expressed as one half of a 95 percent confidence interval.

*e*_c = Relative error of *c*, expressed as one half of a 95 percent confidence interval.

(F) Equation 15 to this paragraph (c)(4)(i)(F) provides the general formula for calculating the relative errors of products.

Equation 15 to Paragraph (c)(4)(i)(F)

$$e_{PR} = \frac{e_{PA}}{(a * b * c)}$$

Where:

*e*_{PR} = Relative error of the product, expressed as one half of a 95 percent confidence interval.

*e*_{PA} = Absolute error of the product, expressed as one half of a 95 percent confidence interval.

*a***b***c* = Product of the variables measured.

(G) Calculate the absolute error of the controlled substance emissions estimate by performing a preliminary estimate of the annual controlled substance emissions of the process using the method in paragraph (c)(4)(i)(H) of this section. Multiply this result by the relative error calculated for the mass of halogen emitted from the process in equation 15 to paragraph (c)(4)(i)(F) of this section.

(H) To estimate the annual controlled substance emissions of the process for

use in the error estimate, apply the methods set forth in paragraphs (c)(4)(ii) through (vii) and (ix) through (xvi) of this section to representative process measurements. If these process measurements represent less than one year of typical process activity, adjust the estimated emissions to account for one year of typical process activity. To estimate the terms FERd, FEP, and FEBk for use in the error estimate for equations 22, 23, and 24 to this section, you must either use emission testing, monitoring of emitted streams, and/or engineering calculations or assessments.

(ii) The total mass of each controlled substance emitted annually from each controlled substance process must be estimated by using equation 16 to this paragraph (c)(4)(ii).

Equation 16 to Paragraph (c)(4)(ii)

$$E_{FCSf} = \sum_{t=1}^n (E_{Rp} + E_{Pp} + E_{Bp})$$

Where:

*E*_{Contp} = Total mass of each controlled substance *p* emitted annually from process *i* (metric tons).

*E*_{Rp}-*F*_{Contp} = Total mass of controlled substance reactant *p* emitted from production process *i* over the period *t* (metric tons, calculated in equation 22 to paragraph (c)(4)(ix) of this section).

*E*_{Pp}-*F*_{Contp} = Total mass of the controlled substance product *p* emitted from production process *i* over the period *t* (metric tons, calculated in equation 23 to paragraph (c)(4)(x) of this section).

*E*_{Bp}-*F*_{Contp} = Total mass of controlled substance byproduct *p* emitted from production process *i* over the period *t* (metric tons, calculated in equation 24 to paragraph (c)(4)(xi) of this section).

n = Number of concentration and flow measurement periods for the year.

(iii) The total mass of halogen emitted from process *i* over the period *t* must be estimated at least monthly by calculating the difference between the total mass of halogen in the reactant(s) (or inputs, for processes that do not involve a chemical reaction) and the total mass of halogen in the product (or outputs, for processes that do not involve a chemical reaction), accounting for the total mass of halogen in any destroyed or recaptured streams that contain reactants, products, or byproducts (or inputs or outputs). This calculation must be performed using equation 17 to this paragraph (c)(4)(iii). An element other than a halogen may be used in the mass-balance equation, provided the element occurs in all of the controlled substances fed into or generated by the process. In this case, the mass fractions of the element in the

reactants, products, and byproducts

must be calculated as appropriate for that element.

Equation 17 to Paragraph (c)(4)(iii)

$$E_H = \sum_1^v (R_D * MFH_{RD}) - P * MFH_P - F_D$$

Where:

E_H = Total mass of halogen emitted from process i over the period t (metric tons).

R_d = Total mass of the halogen-containing reactant d that is fed into process i over the period t (metric tons).

P = Total mass of the halogen-containing product produced by process i over the period t (metric tons).

MFH_{Rd} = Mass fraction of halogen in reactant d, calculated in equation 25 to paragraph (c)(4)(xii) of this section.

MFH_P = Mass fraction of halogen in the product, calculated in equation 26 to paragraph (c)(4)(xiii) of this section.

F_D = Total mass of halogen in destroyed or recaptured streams from process i containing halogen-containing reactants, products, and byproducts over the period t, calculated in equation 18 to paragraph (c)(4)(iv) of this section.

v = Number of halogen-containing reactants fed into process i.

(iv) The mass of total halogen in destroyed or recaptured streams containing halogen-containing reactants, products, and byproducts must be estimated at least monthly using equation 18 to this paragraph (c)(4)(iv) unless you use the alternative approach provided in paragraph (c)(4)(xv) of this section.

Equation 18 to Paragraph (c)(4)(iv)

$$F_D = \sum_{j=1}^q P_j * MFH_P + \sum_{k=1}^u \left[\left(\sum_{j=1}^q B_{kj} + \sum_{l=1}^x B_{kl} \right) * MFH_{Bk} \right] + \sum_{d=1}^v \left(\sum_{j=1}^q R_{dj} * MFH_{Rd} \right)$$

Where:

F_D = Total mass of halogen in destroyed or recaptured streams from process i containing halogen-containing reactants, products, and byproducts over the period t.

P_j = Mass of the halogen-containing product removed from process i in stream j and destroyed over the period t (calculated in equation 19 or 20 to this section).

B_{kj} = Mass of halogen-containing byproduct k removed from process i in stream j and destroyed over the period t (calculated in equation 19 or 20 to this section).

B_{kl} = Mass of halogen-containing byproduct k removed from process i in stream l and recaptured over the period t.

R_{dj} = Mass of halogen-containing reactant d removed from process i in stream j and destroyed over the period t (calculated in equation 19 or 20 to this section).

MFH_{Rd} = Mass fraction of halogen in reactant d, calculated in equation 25 to paragraph (c)(4)(xii) of this section.

MFH_P = Mass fraction of halogen in the product, calculated in equation 26 to paragraph (c)(4)(xiii) of this section.

MFH_{Bk} = Mass fraction of halogen in byproduct k, calculated in equation 27 to paragraph (c)(4)(xiv) of this section.

q = Number of streams destroyed in process i.

x = Number of streams recaptured in process i.

u = Number of halogen-containing byproducts generated in process i.

v = Number of halogen-containing reactants fed into process i.

(v) The mass of each controlled substance removed from process i in stream j and destroyed over the period t (i.e., P_j , B_{kj} , or R_{dj} , as applicable) must be estimated by applying the destruction efficiency of the device that

has been demonstrated for the controlled substance p to controlled substance f using equation 19 to this paragraph (c)(4)(v).

Equation 19 to Paragraph (c)(4)(v)

$$MF_{contpj} = DE_{contp} * C_{contpj} * S_j$$

Where:

MF_{contpj} = Mass of controlled substance p removed from process i in stream j and destroyed over the period t. (This may be P_j , B_{kj} , or R_{dj} , as applicable.)

DE_{contp} = Destruction efficiency of the device that has been demonstrated for controlled substance p in stream j (fraction).

C_{contpj} = Concentration (mass fraction) of controlled substance p in stream j removed from process i and fed into the destruction device over the period t. If this concentration is only a trace concentration, C_{contpj} is equal to zero.

S_j = Mass removed in stream j from process i and fed into the destruction device over the period t (metric tons).

(vi) The mass of each halogen-containing compound that is not a controlled substance and that is removed from process i in stream j and destroyed over the period t (i.e., $P_{>j}$, $B_{>kj}$, or $R_{>dj}$, as applicable) must be estimated using equation 20 to this paragraph (c)(4)(vi).

Equation 20 to Paragraph (c)(4)(vi)

$$M_{hcgj} = C_{HCgj} * S_j$$

Where:

M_{HCgj} = Mass of non-controlled substance halogen-containing compound g removed from process i in stream j and

destroyed over the period t. (This may be P_j , B_{kj} , or R_{dj} , as applicable.)

C_{HCgj} = Concentration (mass fraction) of non-controlled substance halogen-containing compound g in stream j removed from process i and fed into the destruction device over the period t. If this concentration is only a trace concentration, C_{HCgj} is equal to zero.

S_j = Mass removed in stream j from process i and fed into the destruction device over the period t (metric tons).

(vii) The mass of halogen-containing byproduct k removed from process i in stream l and recaptured over the period t must be estimated using equation 21 to this paragraph (c)(4)(vii).

Equation 21 to Paragraph (c)(4)(vii)

$$B_{kl} = C_{Bkl} * S_l$$

Where:

B_{kl} = Mass of halogen-containing byproduct k removed from process i in stream l and recaptured over the period t (metric tons).

C_{Bkl} = Concentration (mass fraction) of halogen-containing byproduct k in stream l removed from process i and recaptured over the period t. If this concentration is only a trace concentration, C_{Bkl} is equal to zero.

S_l = Mass removed in stream l from process i and recaptured over the period t (metric tons).

(viii) To estimate the terms FER_d , FEP , and FEB_k for equations 22, 23, and 24 to this section, you must account for the total mass of halogen emitted, EF , estimated in equation 17 to paragraph (c)(4)(iii) of this section. These emission characterization measurements must meet the requirements in paragraph

(c)(4)(viii)(A), (B), or (C) of this section, as appropriate. The sum of the terms must equal 1. You must document the data and calculations that are used to apportion individual compounds and to estimate FER_d, FEP, and FEB_k. Exclude from your calculations the halogen included in FD. For example, exclude halogen-containing compounds that are not controlled substances and that result from the destruction of controlled substances by any destruction devices (e.g., the mass of HF created by combustion of a chlorofluorocarbon). However, include emissions of controlled substance that survive the destruction process.

(A) If the calculations under paragraph (b)(1)(viii) of this section, or any subsequent measurements and calculations under this subpart, indicate that the process emits 0.1 metric tons controlled substance or more, estimate the emissions from each process vent, considering controls, using the methods in paragraph (c)(1)(i) of this section. You must characterize the emissions of any process vent that emits 0.1 metric tons controlled substance or more as specified in paragraph (d)(4)(iv) of this section.

(B) For other vents, including vents from processes that emit less than 0.1 metric tons of controlled substance, you

must characterize emissions as specified in paragraph (d)(4)(v) of this section.

(C) For halogen emissions that are not accounted for by vent estimates, you must characterize emissions as specified in paragraph (d)(4)(vi) of this section.

(ix) The total mass of halogen-containing reactant d emitted must be estimated at least monthly based on the total halogen emitted and the fraction that consists of halogen-containing reactants using equation 22 to this paragraph (c)(4)(ix). If the halogen-containing reactant d is not a controlled substance, you may assume that FER_d is zero.

Equation 22 to Paragraph (c)(4)(ix)

$$E_{R-it} = \frac{FER_d * E_H}{(\sum_1^v FER_d * MFH_{Rd} + FEP * MFH_P + \sum_{k=1}^u FEB_k * MFH_{Bk})}$$

Where:

E_{R-it} = Total mass of halogen-containing reactant d that is emitted from process i over the period t (metric tons).

FER_d = The fraction of the mass emitted that consists of the halogen-containing reactant d.

E_H = Total mass of halogen emissions from process i over the period t (metric tons), calculated in equation 17 to paragraph (c)(4)(iii) of this section.

FEP = The fraction of the mass emitted that consists of the halogen-containing product.

FEB_k = The fraction of the mass emitted that consists of halogen-containing byproduct k.

MFH_{Rd} = Mass fraction of halogen in reactant d, calculated in equation 25 to paragraph (c)(4)(xii) of this section.

MFH_P = Mass fraction of halogen in the product, calculated in equation 26 to paragraph (c)(4)(xiii) of this section.

MFH_{Bk} = Mass fraction of halogen in byproduct k, calculation in equation 27 to paragraph (c)(4)(xiv) of this section.

u = Number of halogen-containing byproducts generated in process i.

v = Number of halogen-containing reactants fed into process i.

(x) The total mass of halogen-containing product emitted must be estimated at least monthly based on the total halogen emitted and the fraction that consists of halogen-containing products using equation 23 to this paragraph (c)(4)(x). If the halogen-containing product is not a controlled substance, you may assume that FEP is zero.

Equation 23 to Paragraph (c)(4)(x)

$$E_{P-it} = \frac{FEP * E_H}{(\sum_1^v FER_d * MFH_{Rd} + FEP * MFH_P + \sum_{k=1}^u FEB_k * MFH_{Bk})}$$

Where:

E_{P-it} = Total mass of halogen-containing product emitted from process i over the period t (metric tons).

FEP = The fraction of the mass emitted that consists of the halogen-containing product.

E_H = Total mass of halogen emissions from process i over the period t (metric tons), calculated in equation 17 to paragraph (c)(4)(iii) of this section.

FER_d = The fraction of the mass emitted that consists of halogen-containing reactant d.

FEB_k = The fraction of the mass emitted that consists of halogen-containing byproduct k.

MFH_{Rd} = Mass fraction of halogen in reactant d, calculated in equation 25 to paragraph (c)(4)(xii) of this section.

MFH_P = Mass fraction of halogen in the product, calculated in equation 26 to paragraph (c)(4)(xiii) of this section.

MFH_{Bk} = Mass fraction of halogen in byproduct k, calculation in equation 27 to paragraph (c)(4)(xiv) of this section.

u = Number of halogen-containing byproducts generated in process i.

v = Number of halogen-containing reactants fed into process i.

(xi) The total mass of halogen-containing byproduct k emitted must be estimated at least monthly based on the total halogen emitted and the fraction that consists of halogen-containing byproducts using equation 24 to this paragraph (c)(4)(xi). If halogen-containing byproduct k is not a controlled substance, you may assume that FEB_k is zero.

Equation 24 to Paragraph (c)(4)(xi)

$$E_{Bk-it} = \frac{FEB_k * E_H}{(\sum_1^v FER_d * MFH_{Rd} + FEP * MFH_P + \sum_{k=1}^u FEB_k * MFH_{Bk})}$$

Where:

E_{Bk-it} = Total mass of halogen-containing byproduct k emitted from process i over the period t (metric tons).

FEB_k = The fraction of the mass emitted that consists of halogen-containing byproduct k.

FER_d = The fraction of the mass emitted that consists of halogen-containing reactant d.

FEP = The fraction of the mass emitted that consists of the halogen-containing product.

E_H = Total mass of halogen emissions from process i over the period t (metric tons), calculated in equation 17 to paragraph (c)(4)(iii) of this section.

MFH_{Rd} = Mass fraction of halogen in reactant d, calculated in equation 25 to paragraph (c)(4)(xii) of this section.

MFH_P = Mass fraction of halogen in the product, calculated in equation 26 to paragraph (c)(4)(xiii) of this section.

MFH_{Bk} = Mass fraction of halogen in byproduct k, calculation in equation 27 to paragraph (c)(4)(xiv) of this section.

u = Number of halogen-containing byproducts generated in process i.

v = Number of halogen-containing reactants fed into process i.

(xii) The mass fraction of halogen in reactant d must be estimated using equation 25 to this paragraph (c)(4)(xii).

Equation 25 to Paragraph (c)(4)(xii)

$$MFH_{Rd} = MH_{Rd} * \frac{AW_H}{MW_{Rd}}$$

Where:

MFH_{Rd} = Mass fraction of halogen in reactant d (fraction).

MHR_d = Moles halogen per mole of reactant d.

AW_H = Atomic weight of halogen.

MWR_d = Molecular weight of reactant d.

(xiii) The mass fraction of halogen in the product must be estimated using equation 26 to this paragraph (c)(4)(xiii).

Equation 26 to Paragraph (c)(4)(xiii)

$$MFH_P = MH_P * \frac{AW_F}{MW_P}$$

Where:

MFH_P = Mass fraction of halogen in the product (fraction).

MH_P = Moles halogen per mole of product.

AW_H = Atomic weight of halogen.

MW_P = Molecular weight of the product produced.

(xiv) The mass fraction of each applicable halogen in byproduct k must be estimated using equation 27 to this paragraph (c)(4)(xiv).

Equation 27 to Paragraph (c)(4)(xiv)

$$MFH_{Bk} = MH_{Bk} * \frac{AW_F}{MW_{Bk}}$$

Where:

MFH_{Bk} = Mass fraction of halogen in the product (fraction).

MHB_k = Moles halogen per mole of byproduct k.

AW_H = Atomic weight of halogen.

MWB_k = Molecular weight of byproduct k.

(xv) As an alternative to using equation 18 to paragraph (c)(4)(iv) of this section as provided in paragraph (b)(4) of this section, you may estimate at least monthly the total mass of halogen in destroyed or recaptured streams containing halogen-containing compounds (including all halogen-containing reactants, products, and byproducts) using equation 28 to this paragraph (c)(4)(xv).

Equation 28 to Paragraph (c)(4)(xv)

$$F_D = \sum_{j=1}^q DE_{avgj} * c_{THj} * S_j + \sum_{l=1}^x c_{THl} * S_l$$

Where:

F_D = Total mass of halogen in destroyed or recaptured streams from process i containing halogen-containing reactants, products, and byproducts over the period t.

DE_{avgj} = Weighted average destruction efficiency of the destruction device for the halogen-containing compounds identified in destroyed stream j under paragraphs (d)(4)(iv)(B) and (d)(4)(v)(B) of this section (calculated in equation 28 to this paragraph (c)(4)(xv)) (fraction).

c_{THj} = Concentration (mass fraction) of total halogen in stream j removed from

process i and fed into the destruction device over the period t. If this concentration is only a trace concentration, c_{THj} is equal to zero.

S_j = Mass removed in stream j from process i and fed into the destruction device over the period t (metric tons).

c_{THl} = Concentration (mass fraction) of total halogen in stream l removed from process i and recaptured over the period t. If this concentration is only a trace concentration, c_{Bkl} is equal to zero.

S_l = Mass removed in stream l from process i and recaptured over the period t.

q = Number of streams destroyed in process i.

x = Number of streams recaptured in process i.

(xvi) For purposes of equation 28 to paragraph (c)(4)(xv) of this section, calculate the weighted average destruction efficiency applicable to a destroyed stream using equation 29 to this paragraph (c)(4)(xvi).

Equation 29 to Paragraph (c)(4)(xvi)

$$DE_{avgj} = \frac{\sum_{p=1}^w DE_{Contp} * c_{Contpj} * S_j * MFH_{Contp} + \sum_{g=1}^y c_{HCg} * S_j * MFH_g}{\sum_{p=1}^w c_{Contpj} * S_j * MFH_{Contp} + \sum_{g=1}^y c_{HCg} * S_j * MFH_g}$$

Where:

DE_{avgj} = Weighted average destruction efficiency of the destruction device for the halogen-containing compounds identified in destroyed stream j under paragraph (d)(4)(iv)(B) or (d)(4)(v)(B) of this section, as appropriate.

DE_{Contp} = Destruction efficiency of the device that has been demonstrated for controlled substance p in stream j (fraction).

c_{Contpj} = Concentration (mass fraction) of controlled substance p in stream j removed from process i and fed into the destruction device over the period t. If

this concentration is only a trace concentration, c_{Contpj} is equal to zero.

c_{HCg} = Concentration (mass fraction) of non-controlled substance halogen-containing compound g in stream j removed from process i and fed into the destruction device over the period t. If this concentration is only a trace concentration, c_{HCg} is equal to zero.

S_j = Mass removed in stream j from process i and fed into the destruction device over the period t (metric tons).

MFH_{Contp} = Mass fraction of halogen in controlled substance p, calculated in

equation 25, 26, or 27 to this section, as appropriate.

MFH_{HCg} = Mass fraction of halogen in non-controlled substance halogen-containing compound g, calculated in equation 25, 26, or 27 to this section, as appropriate.

w = Number of controlled substances in destroyed stream j.

y = Number of non-controlled substance halogen-containing compounds in destroyed stream j.

(5) Calculate controlled substance emissions from destruction of controlled substances. Estimate annually the total

mass of controlled substances emitted annually from destruction of controlled substances using equation 30 to this paragraph (c)(5):

Equation 30 to Paragraph (c)(5)

$$E_D = RE_D * (1 - DE)$$

Where:

E_D = The mass of controlled substances emitted annually from destruction of controlled substances (kilograms).
 RE_D = The mass of controlled substances that are fed annually into the destruction unit (kilograms).
 DE = Destruction efficiency of the destruction unit (fraction).
 (6) *Effective destruction efficiency for each process.* If using the emission

factor or emission calculation factor method to calculate emissions from the process, use equation 31 to this paragraph (c)(6) to calculate the effective destruction efficiency for the process, including each process vent:

Equation 31 to Paragraph (c)(6)

$$DE_{Effective} = 1 - \frac{\sum_1^w (\sum_1^o \sum_1^v E_{PVP})}{\sum_1^w (\sum_1^o \sum_1^v ECF_{PV-U_p} * (Activity_U + Activity_C)) + \sum_1^w (\sum_1^o \sum_1^v EF_{PV-U_f} * (Activity_U + Activity_C))}$$

Where:

$DE_{Effective}$ = Effective destruction efficiency for process i (fraction).

E_{PVP} = Mass of controlled substance p emitted from process vent v from process i, operating scenario j, for the year, calculated in equation 3, 7, or 8 to this section (kg).

ECF_{PV-U_p} = Emission calculation factor for controlled substance p emitted from process vent v during process i, operating scenario j, as used in equation 7 or 8 to this section (kg emitted/activity) (e.g., kg emitted/kg product), denoted as “ ECF_{PV} ” in those equations.

EF_{PV-U_p} = Emission factor (uncontrolled) for controlled substance p emitted from process vent v during process i, operating scenario j, as used in equation 3 to paragraph (c)(1)(iii)(F) of this section (kg emitted/activity) (e.g., kg emitted/kg product), denoted as “ EF_{PV-U} ” in that equation.

$Activity_U$ = Total process feed, process production, or other process activity for process i, operating scenario j during the year, for which the process vent is not vented to the properly functioning destruction unit (i.e., uncontrolled).

$Activity_C$ = Total process feed, process production, or other process activity for process i, operating scenario j during the year, for which emissions are vented to the properly functioning destruction unit (i.e., controlled).

o = Number of operating scenarios for process i.

v = Number of process vents in process i, operating scenario j.

w = Number of controlled substances emitted from the process.

(d) *Monitoring and QA/QC requirements—(1) Initial scoping speciation to identify controlled substances from transformation processes.* Each entity that transforms controlled substances must conduct an initial scoping speciation to identify all controlled substances that may be generated or emitted from transformation processes that are subject to this section. The entity is not required to quantify emissions under this initial scoping speciation. Only controlled substance products and byproducts that occur in greater than trace concentrations in at least one

stream must be identified under this paragraph (d)(1).

(i) *Procedure.* To conduct the scoping speciation, select the stream(s) (including process streams or destroyed streams) or process vent(s) that would be expected to individually or collectively contain all of the controlled substance byproducts of the process at their maximum concentrations and sample and analyze the contents of these selected streams or process vents. For example, if controlled substance byproducts are separated into one low-boiling-point and one high-boiling-point stream, sample and analyze both of these streams. Alternatively, each entity may sample and analyze streams where controlled substance byproducts occur at less than their maximum concentrations, but the entity must ensure that the sensitivity of the analysis is sufficient to compensate for the expected difference in concentration. For example, if the entity samples and analyzes streams where controlled substance byproducts are expected to occur at one half their maximum concentrations elsewhere in the process, that entity must ensure that the sensitivity of the analysis is sufficient to detect controlled substance byproducts that occur at concentrations of 0.05 percent or higher. The entity does not have to sample and analyze every stream or process vent, i.e., the entity does not have to sample and analyze a stream or process vent that contains only controlled substances that are contained in other streams or process vents that are being sampled and analyzed. Sampling and analysis must be conducted according to the procedures in paragraph (d)(5) of this section.

(ii) *Previous measurements.* If testing of streams (including process streams or destroyed streams) or process vents were conducted less than 5 years before November 12, 2024, and the testing meets the requirements in paragraph (d)(1)(i) of this section, each entity may

use the previous testing to satisfy this requirement.

(2) *Emission factor testing.* If controlled substance emissions are determined using the site-specific process-vent-specific emission factor, each entity must meet the requirements in paragraphs (d)(2)(i) through (vii) of this section.

(i) *Process vent testing.* Conduct an emissions test that is based on representative performance of the process or operating scenario(s) of the process, as applicable. For process vents for which each entity performed an initial scoping speciation, include in the emission test any controlled substance that was identified in the initial scoping speciation. For process vents for which the entity did not perform an initial scoping speciation, include in the emission test any controlled substance that occurs in more than trace concentrations in the vent stream or, where a destruction unit is used, in the inlet to the destruction unit. The entity may include startup and shutdown events if the testing is sufficiently long or comprehensive to ensure that such events are not overrepresented in the emission factor. Malfunction events must not be included in the testing. If the entity does not detect a controlled substance that was identified in the scoping speciation or that occurs in more than trace concentrations in the vent stream or in the inlet to the destruction unit, assume that controlled substance was emitted from the process vent, or from the destruction unit, at a concentration of one third of the detection limit.

(ii) *Number of runs.* For continuous processes, sample the process vent for a minimum of three runs of 1 hour each. If the relative standard deviation (RSD) of the emission factor calculated based on the first three runs is greater than or equal to 0.15 for the emission factor, continue to sample the process vent for an additional three runs of 1 hour each.

(iii) *Process activity measurements.* Determine the mass rate of process feed, process production, or other process

activity as applicable during the test using flow meters, weigh scales, or other measurement devices or instruments with an accuracy and precision of ± 1 percent of full scale or better. These devices may be the same plant instruments or procedures that are used for accounting purposes (such as weigh hoppers, belt weigh feeders, combination of volume measurements and bulk density, etc.) if these devices or procedures meet the requirement. For monitoring ongoing process activity, use flow meters, weigh scales, or other measurement devices or instruments with an accuracy and precision of ± 1 percent of full scale or better.

(iv) *Sample each process.* If process vents from separate processes are manifolded together to a common vent or to a common destruction unit, each entity must follow paragraph (d)(2)(iv)(A), (B), or (C) of this section.

(A) Each entity may sample emissions from each process in the ducts upstream from the point where the emissions are combined.

(B) Each entity may sample in the common duct or at the outlet of the destruction unit when only one process is operating.

(C) Each entity may sample the combined emissions and use engineering calculations and assessments as specified in paragraph (c)(1)(iv) of this section to allocate the emissions to each manifolded process vent, provided the sum of the calculated controlled substance emissions across the individual process vents is within 20 percent of the total controlled substance emissions measured during the manifolded testing.

(v) *Emission test results.* The results of an emission test must include the analysis of samples, number of test runs, the results of the RSD analysis, the analytical method used, determination of emissions, the process activity, and raw data and must identify the process, the operating scenario, the process vents tested, and the controlled substances that were included in the test. The emissions test report must contain all information and data used to derive the process-vent-specific emission factor, as well as key process conditions during the test. Key process conditions include those that are normally monitored for process control purposes and may include but are not limited to yields, pressures, temperatures, etc. (e.g., of reactor vessels, distillation columns).

(vi) *Emissions testing frequency.* Each entity must conduct emissions testing to develop the process-vent-specific emission factor under paragraph (d)(2)(vi)(A) or (B) of this section, whichever occurs first:

(A) *5-year revision.* Conduct an emissions test every 5 years. In the calculations under paragraph (c) of this section, apply the revised process-vent-specific emission factor to the process activity that occurs after the revision.

(B) *Operating scenario change that affects the emission factor.* For planned operating scenario changes, each entity must estimate and compare the emission calculation factors for the changed operating scenario and for the original operating scenario whose process vent specific emission factor was measured. Use the calculation methods in paragraph (c)(1)(iv) of this section. If the emission calculation factor for the changed operating scenario is 15 percent or more different from the emission calculation factor for the previous operating scenario (this includes the cumulative change in the emission calculation factor since the most recent emissions test), the entity must conduct an emissions test to update the process-vent-specific emission factor, unless the difference between the operating scenarios is solely due to the application of a destruction unit to emissions under the changed operating scenario. Conduct the test before February 14 of the calendar year that immediately follows the change. In the calculations under paragraph (c) of this section, apply the revised process-vent-specific emission factor to the process activity that occurs after the operating scenario change.

(vii) *Previous measurements.* If an emissions test was conducted less than 5 years before November 12, 2024, and the emissions testing meets the requirements in paragraphs (d)(2)(i) through (vii) of this section, the entity may use the previous emissions testing to develop process-vent-specific emission factors. For purposes of paragraph (d)(2)(vi)(A) of this section, the date of the previous emissions test rather than November 12, 2024, shall constitute the beginning of the 5-year re-measurement cycle.

(3) *Emission calculation factor monitoring.* If controlled substance emissions were determined using the site-specific process-vent-specific emission calculation factor, each entity must meet the requirements in paragraphs (d)(3)(i) through (iv) of this section.

(i) *Operating scenario.* Perform the emissions calculation for the process vent based on representative performance of the operating scenario of the process. If more than one operating scenario applies to the process that contains the subject process vent, you must conduct a separate emissions calculation for operation under each

operating scenario. For each continuous process vent that contains more than trace concentrations of any controlled substance and for each batch process vent that contains more than trace concentrations of any controlled substance, develop the process-vent-specific emission calculation factor for each operating scenario. For continuous process vents, determine the emissions based on the process activity for the representative performance of the operating scenario. For batch process vents, determine emissions based on the process activity for each typical batch operating scenario.

(ii) *Process activity measurements.* Use flow meters, weigh scales, or other measurement devices or instruments with an accuracy and precision of ± 1 percent of full scale or better for monitoring ongoing process activity.

(iii) *Emission calculation results.* The emission calculation must be documented by identifying the process, the operating scenario, and the process vent(s). The documentation must contain the information and data used to calculate the process-vent-specific emission calculation factor.

(iv) *Operating scenario change that affects the emission calculation factor.* For planned operating scenario changes that are expected to change the process-vent-specific emission calculation factor, each entity must conduct an emissions calculation to update the process-vent-specific emission calculation factor. In the calculations under paragraph (c) of this section, apply the revised emission calculation factor to the process activity that occurs after the operating scenario change.

(v) *Previous calculations.* If an emissions calculation was performed for the process vent and operating scenario less than 5 years before November 12, 2024, and the emissions calculation meets the requirements in paragraphs (c)(1)(iv)(A) and (B) of this section and in paragraphs (d)(3)(i) through (iv) of this section, each entity may use the previous calculation to develop the site-specific process-vent-specific emission calculation factor.

(4) *Mass balance monitoring.* If you determine controlled substance emissions from any process using the mass balance method under paragraph (c)(4) of this section, you must estimate the total mass of each controlled substance emitted from that process at least monthly. Only streams that contain greater than trace concentrations of halogen-containing reactants, products, or byproducts must be monitored under this paragraph (d)(4).

(i) *Mass measurements.* Measure the following masses on a monthly or more

frequent basis using flowmeters, weigh scales, or a combination of volumetric and density measurements with accuracies and precisions that allow the facility to meet the error criteria in paragraph (c)(4)(i) of this section:

(A) Total mass of each halogen-containing product produced. Account for any used halogen-containing product added into the production process upstream of the output measurement as directed at §§ 98.413(b) and 98.414(b) of this chapter.

(B) Total mass of each halogen-containing reactant fed into the process.

(C) The mass removed from the process in each stream fed into the destruction device.

(D) The mass removed from the process in each recaptured stream.

(ii) *Concentration measurements for use with paragraph (c)(4)(iv) of this section.* If you use paragraph (c)(4)(iv) of this section to estimate the mass of halogen in destroyed or recaptured streams, measure the following concentrations at least once each calendar month during which the process is operating, on a schedule to ensure that the measurements are representative of the full range of process conditions (e.g., catalyst age). Measure more frequently if this is necessary to meet the error criteria in paragraph (c)(4)(i) of this section. Use equipment and methods (e.g., gas chromatography) that comply with paragraph (d)(5) of this section and that have an accuracy and precision that allow the facility to meet the error criteria in paragraph (c)(4)(i) of this section. Only halogen-containing reactants, products, and byproducts that occur in a stream in greater than trace concentrations must be monitored under this paragraph (d)(4)(ii).

(A) The concentration (mass fraction) of the halogen-containing product in each stream that is fed into the destruction device.

(B) The concentration (mass fraction) of each halogen-containing byproduct in each stream that is fed into the destruction device.

(C) The concentration (mass fraction) of each halogen-containing reactant in each stream that is fed into the destruction device.

(D) The concentration (mass fraction) of each halogen-containing byproduct in each stream that is recaptured (C_{Bki}).

(iii) *Concentration measurements for use with paragraph (c)(4)(xv) of this section.* If you use paragraph (c)(4)(xv) of this section to estimate the mass of halogen in destroyed or recaptured streams, measure the concentrations listed in paragraphs (d)(4)(iii)(A) and (B) of this section at least once each

calendar month during which the process is operating, on a schedule to ensure that the measurements are representative of the full range of process conditions (e.g., catalyst age). Measure more frequently if this is necessary to meet the error criteria in paragraph (c)(4)(i) of this section. Use equipment and methods (e.g., gas chromatography) that comply with paragraph (d)(5) of this section and that have an accuracy and precision that allow the facility to meet the error criteria in paragraph (c)(4)(i) of this section. Only halogen-containing reactants, products, and byproducts that occur in a stream in greater than trace concentrations must be monitored under this paragraph (d)(4)(iii).

(A) The concentration (mass fraction) of total halogen in each stream that is fed into the destruction device.

(B) The concentration (mass fraction) of total halogen in each stream that is recaptured.

(iv) *Emissions characterization: process vents emitting 0.1 metric tons or more.* To characterize emissions from any process vent emitting 0.1 metric tons of controlled substances or more, comply with paragraphs (d)(4)(iv)(A) through (E) of this section, as appropriate. Only halogen-containing reactants, products, and byproducts that occur in a stream in greater than trace concentrations must be monitored under this paragraph (d)(4)(iv).

(A) *Uncontrolled emissions.* If emissions from the process vent are not routed through a destruction device, sample and analyze emissions at the process vent or stack or sample and analyze emitted streams before the process vent. If the process has more than one operating scenario, you must either perform the emission characterization for each operating scenario or perform the emission characterization for the operating scenario that is expected to have the largest emissions and adjust the emission characterization for other scenarios using engineering calculations and assessments as specified in paragraph (c)(1)(iv) of this section. To perform the characterization, take three samples under conditions that are representative for the operating scenario. Measure the concentration of each halogen-containing compound in each sample. Use equipment and methods that comply with paragraph (d)(5) of this section. Calculate the average concentration of each halogen-containing compound across all three samples.

(B) *Controlled emissions using paragraph (c)(4)(xv) of this section.* If you use paragraph (c)(4)(xv) of this

section to estimate the total mass of halogen in destroyed or recaptured streams, and if the emissions from the process vent are routed through a destruction device, characterize emissions as specified in paragraph (d)(4)(iv)(A) of this section before the destruction device. Apply the destruction efficiency demonstrated for each controlled substance in the destroyed stream to that controlled substance. Exclude from the characterization halogen-containing compounds that are not controlled substances.

(C) *Controlled emissions using paragraph (c)(4)(iv) of this section.* If you use paragraph (c)(4)(iv) of this section to estimate the mass of halogen in destroyed or recaptured streams, and if the emissions from the process vent are routed through a destruction device, characterize the process vent's emissions monthly (or more frequently) using the monthly (or more frequent) measurements under paragraphs (d)(4)(i)(C) and (d)(4)(ii)(A) through (C) of this section. Apply the destruction efficiency demonstrated for each controlled substance in the destroyed stream to that controlled substance. Exclude from the characterization halogen-containing compounds that are not controlled substances.

(D) *Emissions characterization frequency.* You must repeat emission characterizations performed under paragraphs (d)(4)(iv)(A) and (B) of this section under paragraph (d)(4)(iv)(D)(1) or (2) of this section, whichever occurs first:

(1) *5-year revision.* Repeat the emission characterization every 5 years. In the calculations under paragraph (c) of this section, apply the revised emission characterization to the process activity that occurs after the revision.

(2) *Operating scenario change that affects the emission characterization.* For planned operating scenario changes, you must estimate and compare the emission calculation factors for the changed operating scenario and for the original operating scenario whose process vent specific emission factor was measured. Use the engineering calculations and assessments specified in paragraph (c)(1)(iv) of this section. If the share of total halogen-containing compound emissions represented by any controlled substance changes under the changed operating scenario by 15 percent or more of the total, relative to the previous operating scenario (this includes the cumulative change in the emission calculation factor since the last emissions test), you must repeat the emission characterization. Perform the emission characterization before

February 14 of the year that immediately follows the change. In the calculations under paragraph (c) of this section, apply the revised emission characterization to the process activity that occurs after the operating scenario change.

(E) *Subsequent measurements.* If a process vent with controlled substance emissions less than 0.1 metric tons, per paragraph (c)(1)(ii) of this section, is later found to have controlled substance emissions of 0.1 metric tons or greater, you must perform an emission characterization under this paragraph (d)(4)(iv)(E) during the following year.

(v) *Emissions characterization: process vents emitting less than 0.1 metric tons.* To characterize emissions from any process vent emitting less than 0.1 metric tons, comply with paragraphs (d)(4)(v)(A) and (B) of this section, as appropriate. Only halogen-containing reactants, products, and byproducts that occur in a stream in greater than trace concentrations must be monitored under this paragraph (d)(4)(v).

(A) *Uncontrolled emissions.* If emissions from the process vent are not routed through a destruction device, emission measurements must consist of sampling and analysis of emissions at the process vent or stack, sampling and analysis of emitted streams before the process vent, previous test results, provided the tests are representative of current operating conditions of the process, or bench-scale or pilot-scale test data representative of the process operating conditions.

(B) *Controlled emissions using paragraph (c)(4)(xv) of this section.* If you use paragraph (c)(4)(xv) of this section to estimate the total mass of halogen in destroyed or recaptured streams, and if the emissions from the process vent are routed through a destruction device, characterize emissions as specified in paragraph (d)(4)(v)(A) of this section before the destruction device. Apply the destruction efficiency demonstrated for each controlled substance in the destroyed stream to that controlled substance. Exclude from the characterization halogen-containing compounds that are not controlled substances.

(C) *Controlled emissions using paragraph (c)(4)(iv) of this section.* If you use paragraph (c)(4)(iv) of this section to estimate the mass of halogen in destroyed or recaptured streams, and if the emissions from the process vent are routed through a destruction device, characterize the process vent's emissions monthly (or more frequently) using the monthly (or more frequent) measurements under paragraphs

(d)(4)(i)(C) and (d)(4)(ii)(A) through (C) of this section. Apply the destruction efficiency demonstrated for each controlled substance in the destroyed stream to that controlled substance. Exclude from the characterization halogen-containing compounds that are not controlled substances.

(vi) *Emissions characterization: emissions not accounted for by process vent estimates.* Calculate the weighted average emission characterization across the process vents before any destruction devices. Apply the weighted average emission characterization for all the process vents to any halogen emissions that are not accounted for by process vent estimates.

(vii) *Impurities in reactants.* If any halogen-containing impurity is fed into a process along with a reactant (or other input) in greater than trace concentrations, this impurity shall be monitored under this section and included in the calculations under paragraph (c) of this section in the same manner as reactants fed into the process, fed into the destruction device, recaptured, or emitted, except the concentration of the impurity in the mass fed into the process shall be measured, and the mass of the impurity fed into the process shall be calculated as the product of the concentration of the impurity and the mass fed into the process. The mass of the reactant fed into the process may be reduced to account for the mass of the impurity.

(viii) *Alternative to error calculation.* As an alternative to calculating the relative and absolute errors associated with the estimate of emissions under this paragraph (d)(4), you may comply with the precision, accuracy, and measurement and calculation frequency requirements of paragraph (d)(4)(viii)(A) through (C) of this section.

(A) *Mass measurements.* Measure the masses specified in paragraph (d)(4)(i) of this section using flowmeters, weigh scales, or a combination of volumetric and density measurements with accuracies and precisions of ± 0.2 percent of full scale or better.

(B) *Concentration measurements.* Measure the concentrations specified in paragraph (d)(4)(ii) or (iii) of this section, as applicable, using analytical methods with accuracies and precisions of ± 10 percent or better.

(C) *Measurement and calculation frequency.* Perform the mass measurements specified in paragraph (d)(4)(i) of this section and the concentration measurements specified in paragraph (d)(4)(ii) or (iii) of this section, as applicable, at least weekly, and calculate emissions at least weekly.

(5) *Emission and stream testing, including analytical methods.* Select and document testing and analytical methods as follows:

(i) *Sampling and mass measurement for emission testing.* For emission testing in process vents or at the stack, use methods for sampling, measuring volumetric flow rates, non-controlled substance gas analysis, and measuring stack gas moisture that have been validated using a scientifically sound validation protocol.

(A) *Sample and velocity traverses.* Acceptable methods include but are not limited to EPA Method 1 or 1A in appendix A-1 to 40 CFR part 60.

(B) *Velocity and volumetric flow rates.* Acceptable methods include but are not limited to EPA Method 2, 2A, 2B, 2C, 2D, 2F, or 2G in appendix A-1 to 40 CFR part 60. Alternatives that may be used for determining flow rates include Other Test Method 24 (incorporated by reference, see § 82.27) and ALT-012 (incorporated by reference, see § 82.27).

(C) *Non-controlled substance gas analysis.* Acceptable methods include but are not limited to EPA Method 3, 3A, or 3B in appendix A-1 to 40 CFR part 60.

(D) *Stack gas moisture.* Acceptable methods include but are not limited to EPA Method 4 in appendix A-1 to 40 CFR part 60.

(ii) *Analytical methods.* Use a quality-assured analytical measurement technology capable of detecting the analyte of interest at the concentration of interest and use a sampling and analytical procedure validated with the analyte of interest at the concentration of interest. Where calibration standards for the analyte are not available, a chemically similar surrogate may be used. Acceptable analytical measurement technologies include but are not limited to gas chromatography (GC) with an appropriate detector, infrared (IR), Fourier transform infrared (FTIR), and nuclear magnetic resonance (NMR). Acceptable methods for determining controlled substances include EPA Method 18 in appendix A-1 to 40 CFR part 60, EPA Method 320 in appendix A to 40 CFR part 63, EPA 430-R-10-003 (incorporated by reference, see § 82.27), ASTM D6348-03 (incorporated by reference, see § 82.27), or other analytical methods validated using EPA Method 301 at appendix A to 40 CFR part 63. The validation protocol may include analytical technology manufacturer specifications or recommendations.

(iii) *Documentation in the monitoring plan.* Describe the sampling, measurement, and analytical method(s) used under paragraphs (d)(5)(i) and (ii)

of this section in the monitoring plan. Identify the methods used to obtain the samples and measurements listed under paragraphs (d)(5)(i)(A) through (D) of this section. At a minimum, include in the description of the analytical method a description of the analytical measurement equipment and procedures, quantitative estimates of the method's accuracy and precision for the analytes of interest at the concentrations of interest, as well as a description of how these accuracies and precisions were estimated, including the validation protocol used.

(6) *Emission monitoring for pieces of equipment.* If conducting a site-specific leak detection method or monitoring approach for pieces of equipment, each entity must follow paragraph (d)(6)(i) or (ii) of this section and follow paragraph (d)(6)(iii) of this section.

(i) *Site-specific leak monitoring approach.* Each entity may develop a site-specific leak monitoring approach. The entity must validate the leak monitoring method and describe the method and the validation in the monitoring plan. To validate the site-specific method, the entity may, for example, release a known rate of the controlled substances or surrogates of interest, or may compare the results of the site-specific method to those of a method that has been validated for the controlled substances or surrogates of interest. In the description of the leak detection method and its validation, include a detailed description of the method, including the procedures and equipment used and any sampling strategies. Also include the rationale behind the method, including why the method is expected to result in an unbiased estimate of emissions from equipment leaks. If the method is based on methods that are used to detect or quantify leaks or other emissions in other regulations, standards, or guidelines, identify and describe the regulations, standards, or guidelines and why their methods are applicable to emissions of controlled substances or surrogates from leaks. Account for possible sources of error in the method, *e.g.*, instrument detection limits, measurement biases, and sampling biases. Describe validation efforts, including but not limited to any comparisons against standard leaks or concentrations, any comparisons against other methods, and their results. If using the Screening Ranges Approach, the EPA Correlation Approach, or the Unit-Specific Correlation Approach with a monitoring instrument that does not meet all of the specifications in EPA Method 21 in appendix A–7 to 40 CFR part 60, then explain how and why the

monitoring instrument, as used at the facility, would nevertheless be expected to accurately detect and quantify emissions of controlled substances or surrogates from process equipment, and describe how accuracy was verified. For all methods, provide a quantitative estimate of the accuracy and precision of the method.

(ii) *EPA Method 21 monitoring.* If it is determined that EPA Method 21 in appendix A–7 to 40 CFR part 60 is appropriate for monitoring a controlled substance, conduct the screening value concentration measurements using EPA Method 21 to determine the screening range data or the actual screening value data for the Screening Ranges Approach, EPA Correlation Approach, or the Unit-Specific Correlation Approach. For the one-time testing to develop the Unit-Specific Correlation equations in EPA–453/R–95–017 (incorporated by reference, see § 82.27), conduct the screening value concentration measurements using EPA Method 21 and the bagging procedures to measure mass emissions. Concentration measurements of bagged samples must be conducted using gas chromatography following analytical procedures in EPA Method 18 in appendix A–1 to 40 CFR part 60 or other method according to this paragraph (d)(6). Use methane or other appropriate compound as the calibration gas.

(iii) *Frequency of measurement and sampling.* If estimating emissions based on monitoring of equipment, each entity must conduct monitoring at least annually. Sample at least one-third of equipment annually (except for equipment that is unsafe-to-monitor, difficult-to-monitor, insulated, or in heavy liquid service, pumps with dual mechanical seals, agitators with dual mechanical seals, pumps with no external shaft, agitators with no external shaft, pressure relief devices in gas and vapor service with an upstream rupture disk, sampling connection systems with closed-loop or closed purge systems, and pieces of equipment whose leaks are routed through a closed vent system to a destruction unit), changing the sample each year such that at the end of three years, all equipment in the process (that is not subject to the above-listed exceptions) has been monitored. If estimating emissions based on a sample of the equipment in the process, ensure that the sample is representative of the equipment in the process. If there are multiple processes that have similar types of equipment in similar service, and that perform activities on similar controlled substances (in terms of chemical composition, molecular weight, and vapor pressure) at similar

pressures and concentrations, then the entity may annually sample all of the equipment in one third of these processes rather than one third of the equipment in each process.

(7) *Destruction unit performance testing.* If venting or otherwise feeding controlled substances into a destruction unit and apply the destruction efficiency of the device to one or more controlled substances in paragraph (c) of this section, each entity must conduct emissions testing to determine the destruction efficiency for each controlled substance to which the destruction efficiency was applied. The entity must either determine the destruction efficiency for the most-difficult-to-destroy controlled substance fed into the device (or a surrogate that is still more difficult to destroy) and apply that destruction efficiency to all the controlled substances fed into the device or alternatively determine different destruction efficiencies for different groups of controlled substances using the most-difficult-to-destroy controlled substance of each group (or a surrogate that is still more difficult to destroy).

(i) *Destruction efficiency testing.* Each entity must sample the inlet and outlet of the destruction unit for a minimum of three runs of 1 hour each to determine the destruction efficiency. The entity must conduct the emissions testing using the methods in paragraph (d)(5) of this section. To determine the destruction efficiency, emission testing must be conducted when operating at high loads reasonably expected to occur (*i.e.*, representative of high total controlled substance load that will be sent to the device) and when destroying the most-difficult-to-destroy controlled substance (or a surrogate that is still more difficult to destroy) that is fed into the device from the processes subject to this section or that belongs to the group of controlled substances for which destruction efficiency is to be established. If the outlet concentration of a controlled substance that is fed into the device is below the detection limit of the method, the entity may use an outlet concentration of one-third the detection limit to estimate the destruction efficiency.

(A) For all other controlled substances that are vented to the destruction unit in any stream in more than trace concentrations, each entity must test and determine the destruction efficiency achieved for the most-difficult-to-destroy controlled substance or surrogate vented to the destruction unit. Examples of acceptable surrogates include the Class 1 compounds (ranked 1 through 34) in Appendix D, Table D–

1 of "Guidance on Setting Permit Conditions and Reporting Trial Burn Results; Volume II of the Hazardous Waste Incineration Guidance Series," January 1989, EPA Publication EPA 625/6-89/019. A copy of this publication can be obtained by contacting the Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460, (202) 272-0167, <https://www.epa.gov>.

(B) [Reserved]

(ii) *Destruction efficiency testing frequency.* Each entity must conduct emissions testing to determine the destruction efficiency as provided in paragraph (d)(7)(ii)(A) or (B) of this section, whichever occurs first:

(A) *Conduct an emissions test every 5 years.* In the calculations under paragraph (c) of this section, apply the updated destruction efficiency to the destruction that occurs after the test.

(B) *Destruction unit changes that affect the destruction efficiency.* If making a change to the destruction unit that would be expected to affect the destruction efficiency, each entity must conduct an emissions test to update the destruction efficiency. Conduct the test before February 14 of the year that immediately follows the change. In the calculations under paragraph (c) of this section, apply the updated destruction efficiency to the destruction that occurs after the change to the device.

(iii) *Previous testing.* If an emissions test was conducted within the 5 years prior to November 12, 2024, and the emissions testing meets the requirements in paragraph (d)(7)(i) of this section, each entity may use the destruction efficiency determined during this previous emissions testing. For purposes of paragraph (d)(7)(ii)(A) of this section, the date of the previous emissions test rather than November 12, 2024, shall constitute the beginning of the 5-year re-measurement cycle.

(iv) *Hazardous waste combustor testing.* If a destruction unit used to destroy a controlled substance is subject to testing under subpart EEE of part 63 of this chapter or any portion of parts 260 through 270 of this chapter, each entity may apply the destruction efficiency specifically determined for controlled substances under that test if the testing meets the criteria in paragraph (d)(7)(i)(A) of this section. If the testing of the destruction efficiency under subpart EEE of part 63 was conducted more than 5 years ago, the entity may use the most recent destruction efficiency test provided that the design, operation, and maintenance of the destruction unit has not changed since the last destruction efficiency test in a manner that could affect the ability

to achieve the destruction efficiency, and the hazardous waste is fed into the normal flame zone.

(8) *Mass of previously produced controlled substances fed into a destruction unit.* Each entity must measure the mass of each controlled substance that is fed into the destruction unit in more than trace concentrations. Such controlled substances include but are not limited to quantities that are shipped to the facility by another facility for destruction and quantities that are returned to the facility for reclamation but are found to be irretrievably contaminated and are therefore destroyed. The entity must use flowmeters, weigh scales, or a combination of volumetric and density measurements with an accuracy and precision of ± 1 percent of full scale or better. If the measured mass includes more than trace concentrations of materials other than the controlled substance being destroyed, the entity must measure the concentration of the controlled substance being destroyed. The entity must multiply this concentration (mass fraction) by the mass measurement to obtain the mass of the controlled substance fed into the destruction unit.

(9) *Emissions due to malfunctions of destruction unit.* In their estimates of the mass of controlled substances destroyed, facilities that destroy controlled substances must account for any temporary reductions in the destruction efficiency that result from any malfunctions of the destruction unit, including periods of operation outside of the operating conditions defined in operating permit requirements and/or outside of the destruction unit's manufacturer's specifications.

(10) *Emissions due to process startup, shutdown, or malfunctions.* For each process listed in paragraph (b) of this section, each entity must account for emissions of controlled substance that occur at each facility as a result of startups, shutdowns, and malfunctions, either recording controlled substance emissions during these events, or documenting that these events do not result in significant controlled substance emissions. Facilities may use the calculation methods in paragraph (c)(1)(i) of this section to estimate emissions during startups, shutdowns, and malfunctions.

(11) *Development of initial parameters.* Initial scoping specifications, emissions testing, emission factor development, emission calculation factor development, emission characterization development, and destruction efficiency determinations

must be completed by February 7, 2025, for processes and operating scenarios that operate between October 10, 2024, and November 12, 2024. For other processes and operating scenarios, initial scoping specifications, emissions testing, emission factor development, emission calculation factor development, emission characterization development, and destruction efficiency determinations must be complete by February 14 of the year following the year in which the process or operating scenario commences or recommences.

(12) *Calibration for volumetric and density measurements.* Calibrate all flow meters, weigh scales, and combinations of volumetric and density measures using monitoring instruments traceable to the International System of Units (SI) through the National Institute of Standards and Technology (NIST) or other recognized national measurement institute. Recalibrate all flow meters, weigh scales, and combinations of volumetric and density measures at the minimum frequency specified by the manufacturer. Use any of the following applicable flow meter test methods or the calibration procedures specified by the flow meter, weigh-scale, or other volumetric or density measure manufacturer.

(i) ASME MFC-3M-2004 Measurement of Fluid Flow in Pipes Using Orifice, Nozzle, and Venturi (incorporated by reference, see § 82.27).

(ii) ASME MFC-4M-1986 (Reaffirmed 2016) Measurement of Gas Flow by Turbine Meters (incorporated by reference, see § 82.27).

(iii) ASME-MFC-5M-1985, (Reaffirmed 1994) Measurement of Liquid Flow in Closed Conduits Using Transit-Time Ultrasonic Flowmeters (incorporated by reference, see § 82.27).

(iv) ASME MFC-6M-1998 Measurement of Fluid Flow in Pipes Using Vortex Flowmeters (incorporated by reference, see § 82.27).

(v) ASME MFC-7M-1987 (Reaffirmed 1992) Measurement of Gas Flow by Means of Critical Flow Venturi Nozzles (incorporated by reference, see § 82.27).

(vi) ASME MFC-9M-1988 (Reaffirmed 2001) Measurement of Liquid Flow in Closed Conduits by Weighing Method (incorporated by reference, see § 82.27).

(vii) ASME MFC-11M-2006 Measurement of Fluid Flow by Means of Coriolis Mass Flowmeters (incorporated by reference, see § 82.27).

(viii) ASME MFC-14M-2003 Measurement of Fluid Flow Using Small Bore Precision Orifice Meters (incorporated by reference, see § 82.27).

(13) *Calibration for concentration determinations.* All analytical

equipment used to determine the concentration of controlled substances, including but not limited to gas chromatographs and associated detectors, IR, FTIR, and NMR devices, must be calibrated at a frequency needed to support the type of analysis specified in the monitoring plan as required under paragraph (d)(5)(iii) of this section. Quality assurance samples at the concentrations of concern must be used for the calibration. Such quality assurance samples must consist of or be prepared from certified standards of the analytes of concern where available; if not available, calibration must be performed by a method specified in the monitoring plan.

(e) *Data reporting requirements*—(1) *All facilities.* In addition to the information required by § 82.13, for class I controlled substances, and § 82.24, for class II controlled substances, each entity must report the information in paragraphs (e)(1)(ii) through (iv) of this section according to the schedule in paragraph (e)(1)(i) of this section.

(i) *Frequency of reporting under this paragraph (e)(1).* The information in paragraphs (e)(1)(ii) through (v) of this section must be reported annually, as applicable.

(ii) *Process identification.* For each process listed in paragraph (b)(2) of this section, each entity must provide:

(A) A description and identification of the process listed in paragraph (b)(2) of this section.

(B) A description and number, letter, or other identifier for each process vent associated with the process. This identifier must be a consistent name reported from year to year.

(C) The type of method(s) (*i.e.*, process-vent-specific emission factor, process-vent-specific emission calculation factor, or mass balance) and each applicable analytical approach (*e.g.*, compliance options under paragraphs (c)(1)(i) and (d)(4) of this section) used to determine the mass emissions from each process vent associated with the process.

(D) The type of method(s) (*e.g.*, site-specific leak monitoring approach or EPA Method 21 monitoring) and each applicable analytical approach (*e.g.*, compliance options under paragraphs (c)(2)(i) and (d)(4) of this section) used to determine the mass emissions from equipment leaks associated with the process.

(iii) *Process emissions.* For each controlled substance, each entity must report the total mass in kilograms of the controlled substance emitted from the processes listed in paragraph (b)(2) of this section.

(iv) *Effective destruction efficiency.* For each process and controlled substance, report the effective destruction efficiency, $DE_{\text{effective}}$, calculated for that process using equation 31 to paragraph (c)(6) of this section.

(v) *Monitoring plan.* The monitoring plan, as specified in paragraph (f)(6) of this section, including any revisions since the prior year's submission as applicable.

(2) *Reporting for emission factor and emission calculation factor approach.*

For processes whose emissions are determined using the emission factor approach under paragraph (c)(1)(iii) of this section or the emission calculation factor under paragraph (c)(1)(iv) of this section, each entity must report the following for each process.

(i) The identity and quantity of the process activity used to estimate emissions (*e.g.*, tons of product produced or tons of reactant consumed) for each process vent associated with the process.

(ii) The site-specific, process-vent-specific emission factor(s) or emission calculation factor for each process vent associated with the process.

(iii) For each controlled substance, the mass emitted from each process vent associated with the process, in kilograms.

(iv) For each controlled substance, the total mass emitted from equipment leaks, in kilograms.

(3) *Reporting for mass balance approach.* For processes whose emissions are determined using the mass-balance approach under paragraph (c)(4) of this section, you must report the information listed in paragraphs (e)(3)(i) through (xiii) of this section for each process on an annual basis. Identify and separately report controlled substance emissions from transformation processes where the controlled substance reactants are produced at another facility. If you use an element other than a halogen in the mass-balance equation pursuant to paragraph (c)(4)(iii) of this section, substitute that element for the halogen in the reporting requirements of this paragraph (e)(3).

(i) If you calculate the relative and absolute errors under paragraph (c)(4)(i) of this section, the absolute and relative errors calculated under paragraph (c)(4)(i) of this section, as well as the data (including quantities and their accuracies and precisions) used in these calculations.

(ii) The balanced chemical equation that describes the reaction used to manufacture the controlled substance

product and each controlled substance transformation product.

(iii) The mass and chemical formula of each controlled substance reactant emitted from the process in metric tons.

(iv) The mass and chemical formula of the controlled substance product emitted from the process in metric tons.

(v) The mass and chemical formula of each controlled substance byproduct emitted from the process in metric tons.

(vi) The mass and chemical formula of each controlled substance reactant that is fed into the process (metric tons).

(vii) The mass and chemical formula of each halogen-containing product produced by the process (metric tons).

(viii) If you use paragraph (c)(4)(iv) of this section to estimate the total mass of halogen in destroyed or recaptured streams, report the following.

(A) The mass and chemical formula of each halogen-containing product that is removed from the process and fed into the destruction device (metric tons).

(B) The mass and chemical formula of each halogen-containing byproduct that is removed from the process and fed into the destruction device (metric tons).

(C) The mass and chemical formula of each halogen-containing reactant that is removed from the process and fed into the destruction device (metric tons).

(D) The mass and chemical formula of each halogen-containing byproduct that is removed from the process and recaptured (metric tons).

(E) The demonstrated destruction efficiency of the destruction device for each controlled substance fed into the device from the process in greater than trace concentrations (fraction).

(ix) If you use paragraph (c)(4)(xv) of this section to estimate the total mass of halogen in destroyed or recaptured streams, report the following.

(A) The mass of halogen in each stream that is fed into the destruction device (metric tons).

(B) The mass of halogen that is recaptured (metric tons).

(C) The weighted average destruction efficiency of the destruction device calculated for each stream under paragraph (c)(4)(xvi) of this section.

(x) The fraction of the mass emitted that consists of each halogen-containing reactant.

(xi) The fraction of the mass emitted that consists of the halogen-containing product.

(xii) The fraction of the mass emitted that consists of each halogen-containing byproduct.

(xiii) The method used to estimate the total mass of halogen in destroyed or recaptured streams (specify paragraph (c)(4)(iv) or (xv) of this section).

(4) *Reporting of destruction unit excess emission data.* Each facility that destroys a controlled substance must report the excess emissions that result from malfunctions of the destruction unit, and these excess emissions must be reflected in the controlled substance estimates in paragraph (c)(1) of this section. Such excess emissions would occur if the destruction efficiency was reduced due to the malfunction.

(5) *Reporting of destruction unit testing.* By February 7, 2025, or by February 14 of the year immediately following the year in which it begins controlled substance destruction, each facility that destroys controlled substances must submit a report containing the information in paragraphs (e)(5)(i) through (iii) of this section. This report is one-time unless a change is made to the destruction unit that would be expected to affect its destruction efficiencies.

(i) Chemical identity of the controlled substance(s) used in the performance test conducted to determine destruction efficiency, including surrogates, and information on why the surrogate is sufficient to demonstrate the destruction efficiency for each controlled substance, consistent with requirements in paragraph (d)(7)(i) of this section, vented to the destruction unit.

(ii) Date of the most recent destruction unit test.

(iii) Name of all applicable Federal or State regulations that may apply to the destruction process.

(6) *Reporting for destruction.* Each facility that destroys controlled substances must report, separately from the controlled substance emissions reported under paragraph (e)(2) of this section, the following for each previously produced controlled substance destroyed:

(i) The mass of the controlled substance emitted from the destruction unit (kilograms).

(ii) [Reserved]

(7) *Reporting of controlled substance products of incomplete combustion (PICs) of controlled substances.* Each facility that destroys controlled substances must submit a one-time report by February 7, 2025, or by February 14 of the year immediately following the year in which it begins controlled substance destruction, that describes any measurements, research, or analysis that it has performed or obtained that relate to the formation of products of incomplete combustion that are controlled substances during the destruction of controlled substances. The report must include the methods and results of any measurement or modeling studies, including the

products of incomplete combustion for which the exhaust stream was analyzed, as well as copies of relevant scientific papers, if available, or citations of the papers, if they are not. No new testing is required to fulfill the requirement of this paragraph (e)(7).

(f) *Records that must be retained.* Each entity must retain the dated records specified in paragraphs (f)(1) through (6) of this section, as applicable, and be able to provide such information to EPA within 5 business days of the date the records are requested.

(1) *Process information records.* (i) Identify all processes subject to this section. Include the unit identification as appropriate, the process identification reported for the process under paragraphs (e)(1)(ii)(A) through (B) of this section, and the product with which the process is associated.

(ii) Monthly and annual records, as applicable, of all analyses and calculations conducted as required under paragraph (c) of this section, including the data monitored under paragraph (d) of this section, and all information reported as required under paragraph (e) of this section.

(2) *Scoping speciation.* Retain records documenting the information collected under paragraph (d)(1) of this section.

(3) *Emission factor and emission calculation factor method.* Retain the following records for each process for which the emission factor or emission calculation factor method was used to estimate emissions.

(i) Identify all continuous process vents with emissions of controlled substances that are included in the top 25 percent of continuous process vents, and all continuous process vents in the remaining group (*i.e.*, 75 percent of continuous process vents with lower emissions of controlled substances). Include the data and calculation used to develop the preliminary estimate of emissions for each process vent.

(ii) Identify all batch process vents.

(iii) For each vent, identify the method used to develop the factor (*i.e.*, emission factor by emissions test or emission calculation factor).

(iv) The emissions test data and reports (see paragraph (d)(2)(v) of this section) and the calculations used to determine the process-vent-specific emission factor, including the actual process-vent-specific emission factor, the average hourly emission rate of each controlled substance from the process vent during the test and the process feed rate, process production rate, or other process activity rate during the test.

(v) The process-vent-specific emission calculation factor and the calculations

used to determine the process-vent-specific emission calculation factor.

(vi) The annual process production quantity or other process activity information in the appropriate units, along with the dates and time period during which the process was operating and dates and time periods the process vents are vented to the destruction unit. As an alternative to date and time periods when process vents are vented to the destruction unit, a facility may track dates and time periods that process vents by-pass the destruction unit.

(vii) Calculations used to determine annual emissions of each controlled substance for each process and the total controlled substance emissions for all processes, *i.e.*, total for facility.

(4) *Mass-balance method.* Retain the following records for each process for which the mass-balance method was used to estimate emissions. If you use an element other than a halogen in the mass-balance equation pursuant to paragraph (c)(4)(iii) of this section, substitute that element for the halogen in the recordkeeping requirements of this paragraph (f)(4).

(i) The data and calculations used to estimate the absolute and relative errors associated with use of the mass-balance approach.

(ii) The data and calculations used to estimate the mass of halogen emitted from the process.

(iii) The data and calculations used to determine the fractions of the mass emitted consisting of each reactant (FERd), product (FEP), and byproduct (FEBk), including the preliminary calculations in paragraph (c)(4)(viii)(A) of this section.

(5) *Destruction efficiency testing.* A facility that destroys controlled substances and reflects this destruction in paragraph (c) of this section must retain the emissions performance testing reports (including revised reports) for each destruction unit. The emissions performance testing report must contain all information and data used to derive the destruction efficiency for each controlled substance whose destruction the facility reflects in paragraph (c) of this section, as well as the key process and device conditions during the test. This information includes the following:

(i) Destruction efficiency (DE) determined for each controlled substance whose destruction the facility reflects in paragraph (c) of this section, in accordance with paragraph (d)(7)(i)(A) of this section.

(ii) Chemical identity of the controlled substance(s) used in the performance test conducted to determine destruction efficiency,

including surrogates, and information on why the surrogate is sufficient to demonstrate destruction efficiency for each controlled substance, consistent with requirements in paragraph (d)(7)(i)(A) of this section, vented to the destruction unit.

(iii) Mass flow rate of the stream containing the controlled substance or surrogate into the device during the test.

(iv) Concentration (mass fraction) of each controlled substance or surrogate in the stream flowing into the device during the test.

(v) Concentration (mass fraction) of each controlled substance or surrogate at the outlet of the destruction unit during the test.

(vi) Mass flow rate at the outlet of the destruction unit during the test.

(vii) Test methods and analytical methods used to determine the mass flow rates and controlled substance (or surrogate) concentrations of the streams flowing into and out of the destruction unit during the test.

(viii) Destruction unit conditions that are normally monitored for device control, such as temperature, total mass flow rates into the device, and CO or O₂ levels.

(ix) Name of all applicable Federal or State regulations that may apply to the destruction process.

(6) *Equipment leak records.* If the equipment is subject to paragraph (c)(2) of this section, each entity must maintain information on the number of each type of equipment, the service of each piece of equipment (gas, light liquid, heavy liquid); the concentration of each controlled substance in the stream; each piece of equipment excluded from monitoring requirement; the time period each piece of equipment was in service, and the emission calculations for each controlled substance for all processes. Depending on the equipment leak monitoring approach followed, each entity must maintain information for equipment on the associated screening data concentrations for greater than or equal to 10,000 ppmv and associated screening data concentrations for less than 10,000 ppmv; associated actual screening data concentrations; and associated screening data and leak rate data (*i.e.*, bagging) used to develop a unit-specific correlation. If a site-specific leak detection approach was developed and followed, provide the records for monitoring events and the emissions estimation calculations, as appropriate, consistent with the approach for equipment leak emission estimation in the monitoring plan.

(7) *All facilities.* Dated records documenting the initial and periodic

calibration of all analytical equipment used to determine the concentration of controlled substances, including but not limited to gas chromatographs, gas chromatography-mass spectrometry, gas chromatograph-electron capture detector, FTIR, and NMR devices, and all mass measurement equipment such as weigh scales, flowmeters, and volumetric and density measures used to measure the quantities reported under this section, including the industry standards or manufacturer directions used for calibration pursuant to paragraphs (d)(5), (6), (12), and (13) of this section.

(8) *Controlled substance monitoring plan.* A Controlled Substance Monitoring Plan must be completed by February 7, 2025, or within 120 days of the date that an entity first meets the criteria in paragraph (a) of this section.

(i) At a minimum, the monitoring plan shall include the elements listed in this paragraph (f)(8)(i) of this section.

(A) Identification of positions of responsibility (*i.e.*, job titles) for collection of the emission data.

(B) Explanation of the processes and methods used to collect the necessary data for calculations under this section.

(C) Description of the procedures and methods that are used for quality assurance, maintenance, and repair of all continuous monitoring systems, flow meters, and other instrumentation used to provide data for the controlled substances reported under this part.

(ii) The monitoring plan may rely on references to existing corporate documents (*e.g.*, standard operating procedures, quality assurance programs under appendix F to 40 CFR part 60 or appendix B to 40 CFR part 75, and other documents) provided that the elements required by paragraph (f)(8)(i) of this section are easily recognizable.

(iii) The owner or operator shall revise the monitoring as needed to reflect changes in production processes, monitoring instrumentation, and quality assurance procedures; or to improve procedures for the maintenance and repair of monitoring systems to reduce the frequency of monitoring equipment downtime.

■ 7. Add § 82.26 to read as follows:

§ 82.26 Treatment of data submitted under this subpart.

(a) Sections 2.201 through 2.215 and 2.301 of this chapter do not apply to data submitted under this subpart that EPA has determined through rulemaking to be either of the following:

(1) Emission data, as defined in § 2.301(a)(2) of this chapter, determined in accordance with section 114(c) and 307(d) of the Clean Air Act; or

(2) Data not otherwise entitled to confidential treatment.

(b) Except as otherwise provided in paragraph (d) of this section and §§ 2.201 through 2.208 and 2.301(c) and (d) of this chapter do not apply to data submitted under this part that EPA has determined through rulemaking to be entitled to confidential treatment. EPA shall treat that information as confidential in accordance with the provisions of § 2.211 of this chapter, subject to paragraph (d) of this section and § 2.209 of this chapter.

(c) Upon receiving a request under 5 U.S.C. 552 for data submitted under this part that EPA has determined through rulemaking to be entitled to confidential treatment, the relevant Agency official shall furnish the requestor a notice that the information has been determined to be entitled to confidential treatment and that the request is therefore denied. The notice shall include or cite to the appropriate EPA determination.

(d) A determination made through rulemaking that information submitted under this part is entitled to confidential treatment shall continue in effect unless, subsequent to the confidentiality determination through rulemaking, EPA takes one of the following actions:

(1) EPA determines through a subsequent rulemaking that the information is emission data or data not otherwise entitled to confidential treatment; or

(2) The Office of General Counsel issues a final determination, based on the requirements of 5 U.S.C. 552(b)(4), stating that the information is no longer entitled to confidential treatment because of change in the applicable law or newly discovered or changed facts. Prior to making such final determination, EPA shall afford the business an opportunity to submit comments on pertinent issues in the manner described by §§ 2.204(e) and 2.205(b) of this chapter. If, after consideration of any timely comments submitted by the business, the Office of General Counsel makes a revised final determination that the information is not entitled to confidential treatment, the relevant agency official will notify the business in accordance with the procedures described in § 2.205(f)(2) of this chapter.

■ 8. Add § 82.27 to read as follows:

§ 82.27 Incorporation by reference.

(a)(1) Certain material is incorporated by reference 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 incorporation by reference (IBR) material is available

for inspection at EPA and at the National Archives and Records Administration (NARA). Contact EPA at: U.S. EPA's Air and Radiation Docket; EPA West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460, 202-566-1742. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

(2) The IBR material may be obtained from the sources in the following paragraphs of this section or from one or more private resellers listed in this paragraph (a)(2). For material that is no longer commercially available, contact: U.S. EPA's Air and Radiation Docket; EPA West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460; a-and-rdoCKET@epa.gov.

(i) Accuris Standards Store, 321 Inverness Drive, South Englewood, CO 80112; phone: (800) 332-6077; website: <https://accuristech.com>.

(ii) American National Standards Institute (ANSI), 25 West 43rd Street, Fourth Floor, New York, NY 10036-7417; phone: (212) 642-4980; email: info@ansi.org; website: www.ansi.org.

(iii) GlobalSpec, 257 Fuller Road, Suite NFE 1100, Albany, NY 12203-3621; phone: (800) 261-2052; website: <https://standards.globalspec.com>.

(iv) Nimonik Document Center, 401 Roland Way, Suite 224, Oakland, CA 94624; phone (650) 591-7600; email: info@document-center.com; website: www.document-center.com.

(b) American Society of Mechanical Engineers (ASME), Two Park Avenue, New York, NY 10016, phone: 800.843.2763, email: CustomerCare@asme.org; website: www.asme.org.

(1) ASME MFC-3M-2004, Measurement of Fluid Flow in Pipes Using Orifice, Nozzle, and Venturi, issued August 15, 2005; IBR approved for § 82.25(d).

(2) ASME MFC-4M-1986 (Reaffirmed 2016), Measurement of Gas Flow by Turbine Meters, reaffirmed 2016, IBR approved for § 82.25(d).

(3) ASME MFC-5M-1985 (Reaffirmed 1994), Measurement of Liquid Flow in Closed Conduits Using Transit-Time Ultrasonic Flow Meters, copyright 1985; IBR approved for § 82.25(d).

(4) ASME MFC-6M-1998, Measurement of Fluid Flow in Pipes Using Vortex Flowmeters, July 4, 1998; IBR approved for § 82.25(d).

(5) ASME MFC-7M-1987 (Reaffirmed 1992), Measurement of Gas Flow by Means of Critical Flow Venturi Nozzles, copyright 1987; IBR approved for § 82.25(d).

(6) ASME MFC-9M-1988 (Reaffirmed 2001), Measurement of Liquid Flow in Closed Conduits by Weighing Method, reaffirmed 2001; IBR approved for § 82.25(d).

(7) ASME MFC-11M-2006, Measurement of Fluid Flow by Means of Coriolis Mass Flowmeters, issued March 30, 2007; IBR approved for § 82.25(d).

(8) ASME MFC-14M-2003, Measurement of Fluid Flow Using Small Bore Precision Orifice Meters, issued April 17, 2003; IBR approved for § 82.25(d).

(c) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428; phone: 610.832.9500; email: service@astm.org; website: www.astm.org/.

(1) ASTM D6348-03 Standard Test Method for Determination of Gaseous Compounds by Extractive Direct

Interface Fourier Transform Infrared (FTIR) Spectroscopy, approved October 1, 2003, IBR approved for § 82.25(d).

(2) [Reserved]

(d) U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; phone: 202.272.0167; website: www.epa.gov.

(1) Approved Alternative Method 012: An Alternate Procedure for Stack Gas Volumetric Flow Rate Determination (Tracer Gas) (ALT-012), U.S. Environmental Protection Agency Emission Measurement Center, May 23, 1994, IBR approved for § 82.25(d).

(2) Emissions Inventory Improvement Program, Volume II: Chapter 16, Methods for Estimating Air Emissions from Chemical Manufacturing Facilities, August 2007, Final, IBR approved for § 82.25(c).

(3) Protocol for Equipment Leak Emission Estimates, EPA-453/R-95-017, November 1995 (EPA-453/R-95-017), IBR approved for § 82.25(c) and (d).

(4) Protocol for Measuring Destruction or Removal Efficiency (DRE) of Fluorinated Greenhouse Gas Abatement Equipment in Electronics Manufacturing, Version 1, EPA-430-R-10-003, March 2010 (EPA 430-R-10-003), IBR approved for § 82.25 (d).

(5) Tracer Gas Protocol for the Determination of Volumetric Flow Rate Through the Ring Pipe of the Xact Multi-Metals Monitoring System, also known as Other Test Method 24 (Tracer Gas Protocol), Eli Lilly and Company Tippecanoe Laboratories, September 2006, IBR approved for § 82.25(d).

[FR Doc. 2024-22380 Filed 10-9-24; 8:45 am]

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