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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 52

[NRC-2025-0018]

RIN 3150-AL26

Revising the Duration of Design Certifications

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to revise the duration of design certifications (DCs). Specifically, this direct final rule replaces the 15-year duration for DCs with a 40-year duration period, both for existing DCs currently in effect and generically for future DCs, including renewals. This direct final rule does not change the date of issuance or renewal for existing DCs (*i.e.*, the start date by which an existing DC may be referenced remains unchanged). This direct final rule also incorporates a minor editorial correction.

DATES: The final rule is effective September 15, 2025, unless significant adverse comments are received by August 1, 2025. If the direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

ADDRESSES: You may submit comments by any of the following; however, the NRC encourages electronic comment

submission through the Federal rulemaking website:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-0018. Address questions about NRC dockets to Helen Chang; telephone: 301-415-3228; email: Helen.Chang@nrc.gov. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Email comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.

- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. eastern time, Federal workdays; telephone: 301-415-1677.

You can read a plain language description of this direct final rule at <https://www.regulations.gov/docket/NRC-2025-0018>. For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Doyle, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-3748, email: Daniel.Doyle@nrc.gov; or Jordan Glisan, Office of Nuclear Reactor Regulation, telephone: 301-415-3478, email: Jordan.Glisan@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2025-0018 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-0018.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the “Availability of Documents” section of this document.

- **NRC's PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

- **Technical Library:** The Technical Library, which is located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852, is open by appointment only. Interested parties may make appointments to examine documents by contacting the NRC Technical Library by email at Library.Resource@nrc.gov between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include

Docket ID NRC–2025–0018 in your comment submission.

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

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

II. Rulemaking Procedure

Because the NRC considers this action to be non-controversial, the NRC is using the “direct final rule procedure” for this rule. This amendment is effective on September 15, 2025. However, if the NRC receives significant adverse comments on this direct final rule by August 1, 2025, then the NRC will publish a document that withdraws this action and will address the comments received in a subsequent final rule or as otherwise appropriate. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

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

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

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

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

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

(2) The comment proposes a change or an addition to the rule, and it is

apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC staff to make a change (other than editorial) to the rule.

For detailed instructions on filing comments, please see the **ADDRESSES** section of this document.

III. Background

A standard design certification, also referred to simply as a design certification (DC), is a Commission approval by regulation of a final standard design for a nuclear power facility. A DC is codified via rulemaking and is independent of a specific site or an application to construct or operate a plant. An application to construct or operate a plant may reference a DC to take advantage of reviews previously completed by the NRC, though such an application must still address certain site-specific matters. The NRC’s regulations governing DCs are codified in part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), Subpart B, “Standard Design Certifications,” and specific DCs are published as appendices to part 52.

In this direct final rule, the NRC is amending its regulations to revise the duration of DCs, as approved by the Commission in Staff Requirements Memorandum (SRM)–COMDAW–24–0001, “Revising the Duration of Design Certifications,” dated November 14, 2024. Specifically, this direct final rule replaces the 15-year duration period for initial DCs and renewals with a 40-year duration period, both generically and for each DC currently in effect. For DCs currently in effect, the respective date of issuance or renewal (*i.e.*, the start date by which a DC may be referenced) remains unchanged by this direct final rule. Otherwise stated, the 40-year duration period starts upon the date of issuance or renewal of the DC.

Five DCs are currently in effect: appendix A to 10 CFR part 52, “Design Certification Rule for the U.S. Advanced Boiling Water Reactor,” appendix D to 10 CFR part 52, “Design Certification Rule for the AP1000 Design,” appendix E to 10 CFR part 52, “Design Certification Rule for the ESBWR Design,” appendix F to 10 CFR part 52, “Design Certification Rule for the APR1400 Design,” and appendix G to 10 CFR part 52, “Design Certification Rule for NuScale.” Two DCs have expired because no timely renewal applications were submitted in accordance with § 52.57, “Application for renewal.” These are appendix B to 10 CFR part 52, “Design Certification Rule for the System 80 + Design,” and appendix C

to 10 CFR part 52, “Design Certification Rule for the AP600 Design.”

Accordingly, this direct final rule applies to the five DCs currently in effect and does not apply to the two expired DCs.

IV. Discussion

The NRC is amending its regulations to revise the duration of DCs by replacing the 15-year duration for initial DCs and renewals with a 40-year duration period, both generically and for each DC currently in effect, as approved by the Commission in SRM–COMDAW–24–0001, “Revising the Duration of Design Certifications.”¹ The NRC is revising these regulations based on lessons learned from carrying out the DC renewal process. These amendments will reduce unnecessary regulatory burden on applicants and save NRC resources without any reduction in safety or security.

As discussed in the 1989 final rule promulgating 10 CFR part 52, the 15-year duration for DCs was originally intended to allow actual operating experience with a given design to accumulate before the DC either expires or becomes eligible for renewal (54 FR 15372; April 18, 1989). However, experience has shown that the current 15-year certification period does not allow for sufficient time for such operating experience to accumulate prior to a DC either expiring or needing to be renewed to remain effective. In this situation, both the DC renewal applicant and the NRC expend resources involved with the submittal and review of a DC renewal application that does not reflect additional insights derived from the DC being referenced in the licensing context.

In addition, other existing regulations will continue to ensure that codified DCs and the plants referencing them meet safety and security requirements. With respect to generic changes to DC rules, the Commission has existing criteria under § 52.63(a)(1) for determining when it may modify, rescind, or impose new requirements on the certification information for a previously certified design. For example, one way the Commission may make changes to a DC rule is where the change is “necessary to provide adequate protection of the public health and safety or the common defense and security” (10 CFR 52.63(a)(1)(ii)). The Commission may change a DC rule either on its own motion or in response to a petition for rulemaking from any person, including design vendors, and such changes will provide for notice and opportunity for public comment (10 CFR 52.63(a)(2)(ii)). For potential plant-

specific safety or security issues, the Commission may use plant-specific orders, subject to applicable issue finality provisions (e.g., § 52.63(a)(4) for Tier 1 information). In addition, licensees and applicants who reference a DC may also address potential safety or security concerns using the departure process described in the associated DC rule. That is, all DC rules are codified in appendices to part 52 and are structured such that Section VIII of the associated DC rule appendix prescribes an appropriate process for evaluating potential departures from the DC rule, including via a request for a license amendment or exemption. If NRC approval is required, the NRC would evaluate the request using its typical processes.

Accordingly, the change in duration for DCs will provide more time for a design to be referenced in a license application and more time for the design vendor to accumulate construction and actual operating experience before a design vendor would need to submit a renewal application. In addition, it will reduce unnecessary burdens with no reduction in safety or security. Therefore, the NRC is amending its regulations to change the DC duration to 40 years generically in §§ 52.55, 52.57, and 52.61 as well as for DCs currently in effect in the applicable appendices to 10 CFR part 52.

V. Section-by-Section Analysis

The following paragraphs describe the specific changes proposed by this rulemaking.

Section 52.55 Duration of Certification

This direct final rule revises paragraph (a) to result in a finding that a DC is generically valid for 40 years from the date of issuance.

Section 52.57 Application for Renewal

This direct final rule revises paragraph (a) to conform to the change in Section 52.55.

Section 52.61 Duration of Renewal

This direct final rule revises § 52.61 so that the duration of renewal is not more than 40 years.

Appendix A to Part 52 Design Certification Rule for the U.S. Advanced Boiling Water Reactor

This direct final rule revises section VII so that the appendix can be referenced for a period of 40 years.

Appendix D to Part 52 Design Certification Rule for the AP1000 Design

This direct final rule revises section VII so that the appendix can be referenced for a period of 40 years.

Appendix E to Part 52 Design Certification Rule for the ESBWR Design

This direct final rule revises section VII so that the appendix can be referenced for a period of 40 years.

Appendix F to Part 52 Design Certification Rule for the APR1400 Design

This direct final rule revises section VII so that the appendix can be referenced for a period of 40 years. Additionally, it makes a minor editorial correction in section III.E by replacing the word “entirely” with the word “wholly,” consistent with the corresponding language in the appendices for all other currently effective DCs.

Appendix G to Part 52 Design Certification Rule for NuScale

This direct final rule revises section VII so that the appendix can be referenced for a period of 40 years.

VI. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule does not have a significant economic impact on a substantial number of small entities. These amendments will reduce unnecessary regulatory burden on applicants without any reduction in safety or security. This final rule affects only reactor vendors and the licensing and operation of nuclear power plants. These companies do not fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

VII. Regulatory Analysis

The NRC estimates that the rule results in averted costs of approximately \$56.7 million (7 percent net present value (NPV)) in 2024 dollars to the NRC, licensees, and applicants over the 65-year analysis period (2026–2090). Because the NRC does not currently expect any of these existing designs would be renewed beyond this analysis period, i.e., due to assumed technological advancements over this time period, the NPV over a perpetual horizon is the same. The annualized cost savings over the 65-year analysis period are approximately \$4.03 million (7 percent NPV) and \$3.89 million (3 percent NPV) per year. The averted costs are roughly evenly distributed

between the NRC and industry. The NRC considered all five active DCs being renewed multiple times throughout the analysis period based on staff expectations, with averted renewals due to the first 40-year period. In the first 20 years after the rule becomes effective (2026–2045), the NRC estimates that the new 40-year duration will result in averted costs of \$50.5 million to NRC and industry (7 percent NPV) before the first currently effective DC would either expire or need to be renewed in 2046. The generic change to the duration of DCs would also result in averted costs for future design certification applicants and the NRC because of averted renewals. For example, if a licensee or applicant submits a hypothetical design certification between 2026 and 2030, the NRC estimates that this rule would result in averted costs of approximately \$5.5 million to the NRC and industry, though costs would vary depending on the specific year of submittal (7 percent NPV). Therefore, the cost savings reported above may be an underestimate of the actual cost savings. Based on this analysis, the NRC considers this rule to be cost beneficial to both industry and the NRC.

VIII. Backfitting and Issue Finality

The NRC has determined that this direct final rule does not constitute backfitting as defined in the backfit rule (§ 50.109) and is not inconsistent with any applicable issue finality provision in 10 CFR part 52. Increasing the duration for which a design certification is valid does not affect any previously issued licenses. This rule also does not modify, rescind, or impose new requirements on the certification information in an existing standard design certification.

IX. Plain Writing

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

X. Environmental Assessment and Final Finding of No Significant Environmental Impact

The NRC has determined under the National Environmental Policy Act of 1969, as amended (NEPA), and the NRC’s regulations in subpart A, “National Environmental Policy Act; Regulations Implementing Section 102(2),” of 10 CFR part 51,

“Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” that this direct final rule, if confirmed, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The NRC’s environmental assessment and finding of no significant impact is based on the following considerations. As reflected in 10 CFR 51.32(b)(1)–(2) and as discussed in the 2007 final rule amending 10 CFR parts 51 and 52 (72 FR 49352; August 28, 2007), a rule issuing or amending a design certification does not authorize the siting, construction, or operation of a facility referencing any particular design; it only codifies the design in a rule. This codified finding of no significant impact applies to this rule’s changes extending the duration of DCs currently in effect. By the same logic, the NRC also finds that there is no significant impact associated with this rule’s changes to 10 CFR 52.55, 52.57, and 52.61 to generically extend the duration of future DCs. The NRC also considered whether extending the duration of existing DCs could impact the agency’s NEPA consideration of severe accident mitigation design alternatives (SAMDA) for those DCs. Because this rule does not result in any design changes, the NRC concluded, consistent with 10 CFR 51.30(d), that no additional analysis of SAMDAs was necessary at this time, although the NRC will further consider SAMDAs at future points in the licensing process, as appropriate. The NRC will evaluate the environmental impacts and issue an environmental impact statement as appropriate under NEPA as part of any application for the construction and operation of a facility referencing any particular design certification rule.

The determination of this environmental assessment and finding of no significant impact is that there

will be no significant impact from this action. The environmental assessment and finding of no significant impact are available as indicated in the Availability of Documents section.

XI. Paperwork Reduction Act

This final rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget (OMB), approval number 3150–0151.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XII. Regulatory Planning and Review

Executive Order 12866

Executive Order (E.O.) 12866, as amended by E.O.s 14215 (Ensuring Accountability for All agencies) and 13563 (Improving Regulation and Regulatory Review), directs agencies to assess the 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 costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs (OIRA) has designated this direct final rule “a significant regulatory action” as defined under section 3(f) of E.O. 12866, though not economically significant under 3(f)(1). Accordingly, the NRC submitted this direct final rule to OMB for E.O. 12866 review.

Review Under E.O.s 14154, 14192, 14215, and 14300

The NRC has examined this direct final rule and has determined that it is consistent with the policies and directives outlined in E.O. 14154 “Unleashing American Energy,” E.O. 14192, “Unleashing Prosperity Through Deregulation,” E.O. 14215 “Ensuring Accountability for All Agencies,” and E.O. 14300, “Ordering the Reform of the Nuclear Regulatory Commission.” This direct final rule is considered an E.O. 14192 deregulatory action. We estimate that this rule generates \$4.03 million in annualized costs savings at a 7% discount rate, discounted relative to year 2024, over a perpetual time horizon. Details on the estimated costs of this final rule can be found in Section VII. Regulatory Analysis.

XIII. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has found that it does not meet the criteria at 5 U.S.C. 804(2).

XIV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC will revise the duration of design certifications in 10 CFR part 52. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XV. Availability of Documents

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

Document	ADAMS Accession No./ Federal Register citation
Environmental Assessment and Finding of No Significant Impact by the U.S. Nuclear Regulatory Commission Relating to Revising the Duration of Design Certifications, dated May 2025	ML25049A031
SRM-COMDAW-24-0001, “Revising the Duration of Design Certifications,” dated November 14, 2024	ML24319A209
Federal Register notice—Final Rule, “Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors,” dated April 18, 1989	54 FR 15372
Federal Register notice—Final Rule, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” dated August 28, 2007	72 FR 49352
Presidential Memorandum, “Plain Language in Government Writing,” published June 10, 1998	63 FR 31885

Endnotes

¹ For Appendix D to Part 52, “Design Certification Rule for the AP1000 Design,” this rule replaces the 20-year duration (rather than 15-year duration) with a 40-year duration period. The initial duration period was previously extended from 15 years to 20 years for the AP1000 design by direct final rule (86 FR 52593; September 22, 2021).

List of Subjects in 10 CFR Part 52

Administrative practice and procedure, Antitrust, Combined license, Early site permit, Emergency planning, Fees, Inspection, Issue finality, Limited work authorization, Manufacturing license, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Penalties, Reporting and recordkeeping requirements, Standard design, Standard design certification.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 52:

PART 52—LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

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

Authority: Atomic Energy Act of 1954, secs. 103, 104, 147, 149, 161, 181, 182, 183, 185, 186, 189, 223, 234 (42 U.S.C. 2133, 2134, 2167, 2169, 2201, 2231, 2232, 2233, 2235, 2236, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

§ 52.55 [Amended]

■ 2. In § 52.55, amend paragraph (a) by removing the text “15 years”, wherever it appears, and add, in its place, the text “40 years”.

§ 52.57 [Amended]

■ 3. In § 52.57, amend paragraph (a) by removing the text “15-year”, wherever it appears, and add, in its place, the text “40-year”.

§ 52.61 [Amended]

■ 4. In § 52.61, remove the text “15 years”, wherever it appears, and add, in its place, the text “40 years”.

Appendix A to Part 52 [Amended]

■ 5. In appendix A to 10 CFR part 52, in section VII, remove the text “15 years”, wherever it appears, and add, in its place, the text “40 years”.

Appendix D to Part 52 [Amended]

■ 6. In appendix D to 10 CFR part 52, in section VII remove the text “20 years”, wherever it appears, and add, in its place, the text “40 years”.

Appendix E to Part 52 [Amended]

■ 7. In appendix E to 10 CFR part 52, in section VII remove the text “15 years”, wherever it appears, and add, in its place, the text “40 years”.

Appendix F to Part 52 [Amended]

■ 8. In appendix F to 10 CFR part 52:
 ■ a. In section III.E, remove the word “entirely” wherever it appears, and add, in its place, the word “wholly”.
 ■ b. In section VII, remove the text “15 years”, wherever it appears, and add, in its place, the text “40 years”.

Appendix G to Part 52 [Amended]

■ 9. In appendix G to 10 CFR part 52, in section VII remove the text “15 years”, wherever it appears, and add, in its place, the text “40 years”.

For the Nuclear Regulatory Commission.

Dated: June 30, 2025.

Michael King,

Acting Executive Director for Operations.

[FR Doc. 2025–12396 Filed 7–1–25; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Part 460

[EERE–2009–BT–BC–0021]

RIN 1904–AF73

Energy Conservation Standards for Manufactured Housing

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (DOE) is publishing this rule to amend the compliance date for its manufactured housing energy conservation standards. Previously, manufacturers had to comply with these standards on and after July 1, 2025, for Tier 2 homes and 60 days after the issuance of enforcement procedures for Tier 1 homes. DOE is delaying the Tier 2 compliance date to allow DOE more time to consider the proposed enforcement procedures and comments submitted, and to evaluate appropriate next steps that provide clarity for manufacturers and other stakeholders.

DATES: The effective date of this rule is July 2, 2025.

ADDRESSES: The docket for this rulemaking, which includes **Federal Register** notices, public meeting attendee lists and transcripts, if applicable, comments, and other supporting documents and materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at www.regulations.gov/docket/EERE-2009-BT-BC-0021. The docket web page contains instructions on how to access all documents, including public comments, in the docket, as well as a summary of the rulemaking.

FOR FURTHER INFORMATION CONTACT:

Ms. Ani Esenyan, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–4798. Email: ani.esenyan@hq.doe.gov.

Mr. Jeremy Williams, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 441–1288. Email: jeremy.williams@ee.doe.gov.

SUPPLEMENTARY INFORMATION:

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I. Background

The Energy Independence and Security Act of 2007 (“EISA,” Pub. L. 110–140) directs the U.S. Department of Energy (“DOE” or, in context, “the Department”) to establish energy conservation standards for manufactured housing (“MH”). (42 U.S.C. 17071) Manufactured homes are constructed according to a code administered by the U.S. Department of Housing and Urban Development (“HUD Code”). 24 CFR part 3280. See also generally 42 U.S.C. 5401–5426. Structures, such as site-built and modular homes, that are constructed to state, local, or regional building codes

are excluded from the coverage of the HUD Code.

The rulemaking history of the MH energy conservation standards is discussed in the final rule DOE adopted on May 31, 2022 (“May 2022 Final Rule”). 87 FR 32728. In that rule, DOE adopted energy conservation standards for manufactured housing in a new part of the Code of Federal Regulations (“CFR”) under 10 CFR part 460, subparts A, B, and C. Subpart A of 10 CFR part 460 presents generally the scope of the rule and provides definitions of key terms. Subpart B establishes requirements for manufactured homes that relate to climate zones, the building thermal envelope, air sealing, and installation of insulation, based on certain provisions of the 2021 International Energy Conservation Code (“2021 IECC”). Subpart C establishes requirements based on the 2021 IECC related to duct sealing; heating, ventilation, and air conditioning (“HVAC”); service hot water systems; mechanical ventilation fan efficacy; and heating and cooling equipment sizing.

Under the energy conservation standards, the stringency of the requirements under subpart B is based on a tiered approach depending on the number of sections of the manufactured home. Accordingly, two sets of standards are established in subpart B (*i.e.*, Tier 1 and Tier 2). Both Tier 1 and Tier 2 incorporate building thermal envelope measures based on certain thermal envelope components subject to the 2021 IECC that DOE determined applicable and appropriate for manufactured homes. Tier 1 applies these building thermal envelope provisions to single-section manufactured homes but only includes components at stringencies that would increase the incremental purchase price by less than \$750 in order to address affordability concerns that were raised by HUD and other stakeholders during the consultation and rulemaking process. Tier 2 applies these same building thermal envelope provisions to multi-section manufactured homes but at higher stringencies specified for site-built homes in the 2021 IECC based on consideration of the design and factory construction techniques of manufactured homes. Manufacturers can comply with the building thermal envelope requirements through a *prescriptive* pathway (*e.g.*, using materials with specified ratings) or a *performance* pathway based on overall thermal transmittance (U_o). See 10 CFR 460.102(c). Further, the energy conservation standards for both tiers also include duct and air sealing,

insulation installation, HVAC and service hot water system specifications, mechanical ventilation fan efficacy, and heating and cooling equipment sizing provisions, based on the 2021 IECC. DOE concluded that this approach is cost-effective based on the expected total life-cycle cost (“LCC”) savings for the lifetime of the home associated with implementation of the energy conservation standards. *See e.g.*, 87 FR 32742.

In the May 2022 Final Rule, DOE adopted a compliance date such that the standards would apply to manufactured homes that are manufactured on or after one year following the publication date of the final rule in the **Federal Register**, which was May 31, 2023. In doing so, DOE noted its belief that many manufacturers already have experience complying with efficiency requirements similar to what DOE required in the May 2022 Final Rule based on manufacturers’ previous experience with U_o requirements, as historically relied upon under the broader HUD standards for manufactured housing, and ENERGY STAR Version 2 efficiency requirements for homes produced on or after June 1, 2020. 87 FR 32759. DOE did not specify its approach for enforcement of the standards in the May 2022 Final Rule and stated that manufacturers would be able to comply with the standards as they were issued. DOE posited that many of the requirements in the standards would require minimal compliance efforts (*e.g.*, documenting the use of materials subject to separate Federal or industry standards, such as the R-value of insulation or U-factor values for fenestration). 87 FR 32758, 32790. Nevertheless, DOE noted in the May 2022 Final Rule that it may address compliance and enforcement issues and procedures in a future agency action (*see* 87 FR 32757–32758).

On March 24, 2023, DOE published in the **Federal Register** a Notice of Proposed Rulemaking (NPR) proposing to amend the compliance date for the manufactured housing energy conservation standards (88 FR 17745, “March 2023 NPR”). In that NPR, DOE described the need to amend the compliance date for the manufactured housing standards, noting that it had not yet issued procedures for investigating and enforcing against noncompliance with the standards, and that a delay was necessary to ensure that DOE could receive and incorporate meaningful stakeholder feedback into its enforcement procedures prior to part 460’s compliance date. Accordingly, DOE proposed to require compliance with the Tier 1 standards beginning 60

days after publication of its final enforcement procedures, and compliance with the Tier 2 standards beginning 180 days after publication of its final enforcement procedures. 88 FR 17746.

In a final rule published on May 30, 2023, DOE amended the compliance date for 10 CFR part 460 consistent with its proposed compliance date in the March 23, 2023, NPR for Tier 1 (*i.e.*, 60 days after issuance of DOE’s enforcement procedures for part 460). (88 FR 34411, “May 2023 Final Rule”) However, for Tier 2, DOE amended the compliance date to July 1, 2025. After consideration of comments received in response to the March 2023 NPR, in the May 2023 Final Rule DOE determined that amending the compliance date to July 1, 2025, for Tier 2 homes would provide greater certainty for manufacturers versus an indeterminate date.

DOE published a NPR on December 26, 2023, proposing enforcement procedures for manufactured homes (88 FR 88844, “December 2023 Enforcement NPR”). DOE is continuing to consider the proposed enforcement procedures and comments submitted and has not yet published a final rule establishing enforcement procedures.

DOE published a NPR on April 24, 2025 (“April 2025 NPR”) (90 FR 17230) proposing to extend the compliance date for Tier 2 homes under the manufactured housing energy conservation standards in 10 CFR part 460 until after DOE’s forthcoming enforcement procedures take effect.

II. Need To Amend Compliance Date

In the March 2023 NPR and subsequently-adopted May 2023 Final Rule, DOE recognized that additional lead time for MH manufacturers to comply with the energy conservation standards until after the issuance of enforcement procedures was appropriate, particularly for Tier 2 homes. Indeed, consistent with this approach, and as previously noted, DOE initially proposed in the March 2023 NPR providing a staggered conditional compliance date—for Tier 1 homes, 60 days after publication of its final enforcement procedures, and for Tier 2 homes, 180 days after publication of its final enforcement procedures. 88 FR 17746.

While DOE continues to consider the proposed enforcement procedures and comments submitted, and evaluate appropriate next steps, DOE recognizes there is a possibility that the cadence for compliance dates could become misaligned, *i.e.*, compliance with the more stringent, multi-section Tier 2 standards could be required before the

less stringent, single section Tier 1 standards (and before publication of final enforcement procedures). While DOE previously stated that it believes manufacturers are capable of complying with the DOE standards as written, DOE nevertheless recognizes that having enforcement procedures in place prior to requiring compliance would help provide clarity to manufacturers. DOE is extending the compliance date here consistent with its intent that the Tier 2 compliance deadline occurs after both the Tier 1 compliance deadline and the promulgation of final enforcement procedures.

A delay of the July 1, 2025, compliance date is therefore necessary to ensure that DOE can evaluate and incorporate meaningful stakeholder feedback regarding appropriate next steps for the manufactured housing standard enforcement procedures, while still providing appropriate lead time for compliance.

III. Overview of the Final Rule

Through this action, DOE is finalizing the April 2025 NOPR. Pursuant to its

authority to establish energy conservation standards for manufactured housing (42 U.S.C. 17071), DOE is extending the compliance date for Tier 2 homes under the manufactured housing energy conservation standards in 10 CFR part 460 until after DOE’s forthcoming enforcement procedures take effect. More specifically, DOE is requiring compliance with the Tier 2 standards in subparts B and C beginning 180 days after publication of its final enforcement procedures. DOE is not amending the compliance date for Tier 1 homes. Such homes will be subject to the standards in subparts B and C beginning 60 days after publication of DOE’s final enforcement procedures. This aligns with the proposal in the March 2023 NOPR.

DOE believes enforcement procedures will provide additional clarity to manufacturers and consumers regarding DOE’s expectations of manufacturers and DOE’s plans for enforcing the standards. Delaying the compliance date until after the enforcement procedures

are effective also provides manufacturers time to understand DOE’s enforcement procedures and prepare their operations to ensure compliance with DOE’s standards. Accordingly, DOE is delaying the July 1, 2025, compliance date for the standards of 10 CFR part 460 applicable to Tier 2 homes until 180 days after DOE’s publication of its final enforcement procedures. The existing compliance date for Tier 1 homes will remain unchanged at 60 days after publication of DOE’s final enforcement procedures.

A. Summary of Public Comments

DOE received public comments in response to the April 2025 NOPR from the organizations and interested parties identified in the table below. These comments are available for review in the public docket for this rulemaking. The specific issues relating to the NOPR and this final rule are addressed in the following section (“Discussion of Public Comments Received”).

TABLE III–1—APRIL 2025 NOPR WRITTEN COMMENTS

Commenter(s)	Document No.
Individual *	EERE–2009–BT–BC–0021–2642
Individual	EERE–2009–BT–BC–0021–2643
Manufactured Housing Association for Regulatory Reform	EERE–2009–BT–BC–0021–2644
Individual	EERE–2009–BT–BC–0021–2645
Manufactured Housing Institute	EERE–2009–BT–BC–0021–2647
Joint Comments:	EERE–2009–BT–BC–0021–2646
American Council for an Energy Efficiency Economy, American Institute of Architects, Americans for Financial Reform Education Fund, E4TheFuture, Earth Advantage, Earthjustice, Institute for Market Transformation, Lincoln Institute of Land Policy, Next Step Network, Northeast Energy Efficiency and Electrification Council, NPHS, ROC USA, Sierra Club, Vermont Law and Graduate School, Institute for Energy and the Environment.	

* Comment submitted anonymously.

B. Discussion of Public Comments Received

Comment: Two commenters (Abigail Johnson and an anonymous individual) expressed opposition to DOE’s proposal to delay the Tier 2 compliance date. The anonymous commenter recommended not delaying the energy conservation standards for manufactured housing because the rule will help reduce waste, fraud, and abuse by developers, realtors and government officials interested in protecting the fossil fuel industry. (Anonymous, No. 2642 at p. 1) Abigail Johnson opposed this extension based on an expressed concern with deregulation and with the executive order that prompted this change as it relates to manufactured housing. She noted that the current standards were established in 2023 and believed there

has been sufficient time to figure out a system of enforcement. Further, she stated stricter standards are necessary to address the climate crisis, and also expressed concern with federal workforce reduction in the area of regulation and safety and that a delay of the conservation deadline may make it an ever-moving goal with no actual implementation. (Abigail Johnson, No. 2643 at p. 1)

Response: Although DOE understands the commenters’ interest in enforcing the standards, DOE’s conclusion, consistent with that in the May 2023 Final Rule, is that compliance with the standards is better accomplished by first having enforcement procedures in place to provide added clarity to manufacturers.

Comment: Manufactured Housing Association for Regulatory Reform

(“MHARR”) commented that it supports an indefinite extension and delay of the implementation and compliance dates for both the Tier 1 and Tier 2 energy standards. In addition, MHARR reiterated positions previously submitted to the Department regarding DOE’s initial extension proposal, and through which MHARR advocated for extending the energy standards compliance date, stressing that it is necessary to develop comprehensive testing, enforcement, and regulatory compliance criteria, which are essential components of any standard. They also commented that the extension is crucial to effectively consider the costs of these measures, both individually and in relation to the overall expenses of manufactured housing energy standards and enforcement procedures. MHARR also referenced pending litigation

surrounding DOE's energy conservation standards for manufactured housing filed in the Western District of Texas.

While MHARR commented it supports extending and delaying manufactured housing energy standards implementation, they also maintain the May 2022 Final Rule standards are fundamentally flawed and should be completely withdrawn, not just postponed. They argue that these standards are detrimental to the manufactured housing industry and hinder affordable homeownership for lower and moderate-income Americans. MHARR advocates for crafting a new, cost-effective rule in collaboration with U.S. Department of Housing and Urban Development ("HUD") and its Manufactured Housing Consensus Committee ("MHCC"), encompassing both the standards and regulatory compliance procedures. (MHARR, No. 2644 at p. 2–3)

Response: DOE agrees with the commenter that it is necessary to amend the compliance date for Tier 2 homes. DOE understands that, while 3 years have passed since the May 2022 Final Rule, many manufacturers may need additional time to adjust their manufacturing practices and ensure homes are compliant with the updated standards and in a manner consistent with the forthcoming enforcement procedures. The extended compliance lead time established under this final rule will provide additional time for DOE to issue its enforcement procedures, and for manufacturers to continue modifying their practices in anticipation of complying with the standards. DOE addresses the additional information the commenter provided regarding the substance of the standards at the end of this section.

Comment: Fourteen organizations—a combination of energy efficiency, affordable housing, academic, and environmental organizations—together filed joint comments ("Joint Commenters") expressing opposition to DOE's proposed compliance date extension. These organizations contend that the delay will lock-in low-to-moderate-income families into higher utility bills and cause unnecessary increased peak demand on the utility grid, particularly in rural areas. They also noted manufacturer facilities are already capable of complying with the DOE energy conservation standards for manufactured housing and stated that the nation's largest manufacturer has switched all 39 factories in the U.S. to build Zero Energy Ready Homes, which achieved levels of energy efficiency and performance far better than DOE's minimum standard for manufactured

homes. The Joint Commenters stated they would like to retain the fixed date for compliance to avoid lengthy delay of enforcement and, if DOE cannot maintain a fixed date for compliance, any delay tied to publication of enforcement procedures should be consistent with that for Tier 1 homes, that is at no more than 60 days after enforcement procedures are finalized (i.e., the same timeline for both Tier 1 and 2 homes). Additionally, the Joint Commenters would like DOE to begin work on strengthening standards based on the 2024 International Energy Conservation Code (IECC) and further assist manufacturers with building Zero Energy Ready Homes.

Response: DOE disagrees that additional time is unwarranted for manufacturers to comply with the updated energy conservation standards. While many manufacturers may indeed be able to comply with the standards now, some manufacturers may not have a clear picture as to how DOE will evaluate compliance or conduct enforcement procedures. As noted in the April 2025 NOPR, DOE believes that having enforcement procedures in place prior to requiring compliance would help provide clarity to manufacturers. Accordingly, DOE has determined that a delay of the compliance date until after promulgation of enforcement procedures is warranted because DOE believes that clear standards with workable enforcement procedures will best support the full realization of the benefits associated with its energy conservation standards. DOE notes that some benefits (both monetary and non-monetary) may be sacrificed in delaying implementation of the standards, as highlighted by the commenter. However, these net benefits also require additional upfront costs paid by homeowners, which can also have a significant impact on housing affordability. Potential benefits may also not be fully realized if manufacturers do not fully comply with the amended standards and lack clarity on associated enforcement processes. With respect to the difference between the compliance dates for Tier 1 and Tier 2 homes, DOE has previously recognized that the Tier 2 standards are inherently more stringent (compared to the Tier 1 standards), and has determined that additional time is warranted for manufacturers to make adjustments to their operations and practices to ensure compliance with the Tier 2 standards.

Comment: Robert Peeks commented in support of postponing the rule's compliance dates, noting that the current enforcement provisions are not well-aligned with industry obligations

under HUD 3280. He commented on the importance of having effective and workable DOE energy efficiency standards and anticipates improvements to the rule language through future rulemaking activities. (Robert Peeks, No. 2645, at p.1.)

Response: DOE appreciates the commenters' feedback and has taken it into consideration in developing the current final rule. DOE addresses the additional information the commenter provided regarding the substance of the standards at the end of this section.

Comment: The Manufactured Housing Institute ("MHI") commented in support of DOE's proposal to delay compliance for Tier 2 homes. MHI further contends that DOE should delay compliance for both Tier 1 and Tier 2 homes to 3–5 years after finalization of enforcement procedures to align with the typical compliance and implementation periods established under DOE's energy conservation standards for appliances. MHI commented that DOE should at least start anew the 1-year implementation period of the May 2022 Final Rule for both Tier 1 and Tier 2 homes after finalization of testing, compliance, and enforcement ("TCE") provisions and any required 2025 revision to the May 2022 Final Rule. (MHI 2647 p. 1, 4)

Beyond the proposed compliance date extension, MHI stated that DOE should go further and withdraw the May 2022 Final Rule entirely and re-evaluate its cost-benefit analysis based on both a reasoned consideration of the cost of TCE and to reflect up-to-date costing information, consulting with HUD and MHCC as required under EISA. In addition, MHI requests withdraw/reconsideration under Presidential Memorandum: "Delivering Emergency Price Relief for American Families and Deflating the Cost-of-Living Crises" requiring DOE is to deliver price relief to American consumers and lower the cost of housing and expand housing supply. MHI indicates this would also be consistent with E.O. 14192 "Unleashing Prosperity Through Deregulation". (MHI 2647 p. 1–2)

Further, MHI comments that in 2023 DOE recognized the cost and burden of meeting updated building codes, including the 2021 IECC, as related to financial assistance provided by DOE under the Inflation Reduction Act ("IRA"). MHI references DOE's recent notice of intent and request for information with regard to state building code updates, as established under IRA Section 50131. (MHI, No. 2647, Attachment 7, MHI, No. 2647, Attachment 8) and provides this as contrast to energy conservation

standards for manufactured housing and pending enforcement provisions that would require the MH manufactures to redesign floor plans and have designs reapproved by third-party design inspection agencies to meet similar requirements. Based on this, they conclude that a 3–5 year implementation period is warranted after issuance of the final TCE provisions. They also noted that DOE's draft 5-year Appliance rulemaking schedule (MHI, No. 2647, Attachment 8) provides for 3–5 year implementation periods for standards for much simpler building components. MHI also believes that EISA requirements would not prohibit a 3–5 year implementation period, and would not constrain DOE's ability to update standards in accordance with the IECC, as directed under EISA. (MHI 2647 p. 5)

In addition, MHI provided a collection of reference documents, data and details of comments submitted on previous DOE and HUD actions, as well as documents MHI has submitted as part of their related litigation of DOE's energy conservation standards for manufactured housing.

Response: DOE agrees that additional time is warranted for manufacturers to comply with the updated energy conservation standards. While many manufacturers may indeed be able to comply with the standards now, some manufacturers may not have a clear picture as to how DOE will evaluate compliance or conduct enforcement procedures. As noted in the April 2025 NOPR, DOE believes that having enforcement procedures in place prior to requiring compliance would help provide clarity to manufacturers. Accordingly, DOE has determined that a delay of the compliance date until after promulgation of enforcement procedures is warranted. As DOE previously responded to this comment from MHI in the May 2023 Final Rule, DOE disagrees that such an extended period is needed at this time. DOE believes that the compliance lead times in this final rule provide additional time for DOE to issue its enforcement procedures, and for manufacturers to continue modifying their practices to comply with the updated standards.

DOE's emphasizes that the only action DOE is taking in this final rule is to amend the compliance date for Tier 2 manufactured homes. Several commenters expressed opinions and reiterated positions related to DOE's energy conservation standards for manufactured housing, but these comments are outside of the scope of the specific action proposed in the April 2025 NOPR and established through the

current final rule. DOE agrees with commenters that enforcement procedures are necessary and will help provide additional clarity to manufacturers. While DOE fully reviewed and considered all comments received, some of the issues presented may be appropriate for future updates to DOE's energy conservation standards for manufactured housing.

DOE sincerely appreciates the time and input provided by all commenters in response to the current action, as well as previous actions. Robust stakeholder response and participation helps improve the process and leads to clearer and more workable energy conservation standards for manufactured housing.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

Executive Order (“E.O.”) 12866, “Regulatory Planning and Review,” 58 FR 51735 (Oct. 4, 1993), as supplemented and reaffirmed by E.O. 13563, “Improving Regulation and Regulatory Review,” 76 FR 3821 (Jan. 21, 2011), requires agencies, to the extent permitted by law, to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public. DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs (“OIRA”) in the Office of Management and Budget (“OMB”) has emphasized

that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, this regulatory action is consistent with these principles.

Section 6(a) of E.O. 12866 also requires agencies to submit “significant regulatory actions” to OIRA for review. OIRA has determined that this regulatory action constitutes a “significant regulatory action” under section 3(f) of E.O. 12866. Accordingly, this action was submitted to OIRA for review under E.O. 12866.

B. Review Under Executive Orders 14154 and 14192

DOE has examined this rulemaking and has determined that it is consistent with the policies and directives outlined in E.O. 14154 “Unleashing American Energy,” E.O. 14192, “Unleashing Prosperity Through Deregulation,” and Presidential Memorandum, “Delivering Emergency Price Relief for American Families and Defeating the Cost-of-Living Crisis.” This final rule is considered an E.O. 14192 deregulatory action. DOE did not estimate the cost savings of this final rule.

C. Review Under Additional Executive Orders and Procedural Requirements

DOE has concluded that the determinations made pursuant to the various other procedural requirements applicable to the May 2022 Final Rule remain unchanged for this confirmation of that rule. These determinations are set forth in the May 2022 Final Rule. 87 FR 32728, 32809–32817.

V. Approval of the Office of the Secretary

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

List of Subjects in 10 CFR Part 460

Administrative practice and procedure, Buildings and facilities, Energy conservation, Housing standards, Reporting and recordkeeping requirements.

Signing Authority

This document of the Department of Energy was signed on June 26, 2025 by Louis Hrkman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal

Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on June 30, 2025.

Treena V. Garrett,

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

For the reasons stated in the preamble, DOE is amending part 460 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 460—ENERGY CONSERVATION STANDARDS FOR MANUFACTURED HOMES

■ 1. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 17071; 42 U.S.C. 7101 *et seq.*

■ 2. Revise § 460.1 to read as follows:

§ 460.1 Scope.

This subpart establishes energy conservation standards for manufactured homes as manufactured at the factory, prior to distribution in commerce for sale or installation in the field. Manufacturers must apply the requirements of this part to a manufactured home subject to § 460.4(b) that is manufactured on or after 60 days after publication of final enforcement procedures for this part. DOE will amend this section to include the specific compliance date, once known. Manufacturers must apply the requirements of this part to a manufactured home subject to § 460.4(c) that is manufactured on or after 180 days after publication of final enforcement procedures for this part. DOE will amend this section to include the specific compliance date, once known.

[FR Doc. 2025–12328 Filed 7–1–25; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF COMMERCE

Economic Development Administration

13 CFR Part 301

[Docket No.: 250623–0111]

RIN 0610–AA77

Elimination of Supplementary Grant Regulation

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Final rule.

SUMMARY: Through this final rule, the Economic Development Administration (EDA), U.S. Department of Commerce, is eliminating the regulations on supplementary investment assistance. The regulation is confusing and does not provide any guidance in addition to what is already in section 205 of EDA's enabling statute, the Public Works, and Economic Development Act of 1965.

DATES: This rule is effective July 2, 2025.

FOR FURTHER INFORMATION CONTACT: Jeffrey Roberson, Chief Counsel, Office of the Chief Counsel, Economic Development Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Suite 72023, Washington, DC 20230; telephone: (202) 482–1315; email: jroberson@eda.gov.

SUPPLEMENTARY INFORMATION:

Background

EDA's enabling statute is the Public Works and Economic Development Act of 1965 (PWEDA) and EDA's regulations are codified at 13 CFR Chapter III. 13 CFR 301.6 is intended to implement Section 205 of PWEDA which provides that, pursuant to a request by an eligible applicant, EDA may supplement a grant awarded by another "designated federal grant program," provided the eligible applicant qualifies for financial assistance under such program but is unable to supply the required matching share because of its economic situation. However, this regulation has proved to be confusing to the public because it does not provide guidance beyond what is in the law itself. Therefore, EDA is eliminating the superfluous regulation located at 13 CFR 301.6 as it is unnecessary and burdensome to have the public try to ascertain the intent of the regulation, when in fact there is none.

Classification

Administrative Procedure Act and Regulatory Flexibility Act

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment are unnecessary. This rule removes a superfluous regulation that does not provide any additional guidance beyond what is already in section 205 of PWEDA. Therefore, public comment would serve no purpose and is unnecessary. There is also good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness as this rule does not alter the rights or responsibilities of any party, and delaying implementation of this rule and keeping the superfluous regulation may continue to cause confusion.

Because prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis has not been prepared.

Executive Orders No. 12866, 13563, and 14192

This final rule was drafted in accordance with Executive Orders 12866, 13563, and 14192. OMB has determined that this rule is not significant for purposes of Executive Orders 12866 and 13563. This final rule is deregulatory pursuant to Executive Order 14192.

Congressional Review Act

This final rule is not major under the Congressional Review Act (5 U.S.C. 801 *et seq.*).

Executive Order No. 13132

This final rule does not contain policies that have federalism implications.

Paperwork Reduction Act

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

List of Subjects in 13 CFR Part 301.6

Community development, Grant programs-housing and community development.

For the reasons discussed above, EDA amends 13 CFR part 301 as follows:

PART 301—ELIGIBILITY, INVESTMENT RATE AND APPLICATION REQUIREMENTS

- 1. The authority citation for part 301 continues to read as follows:

Authority: 42 U.S.C. 3121; 42 U.S.C. 3141–3147; 42 U.S.C. 3149; 42 U.S.C. 3161; 42 U.S.C. 3175; 42 U.S.C. 3192; 42 U.S.C. 3194; 42 U.S.C. 3211; 42 U.S.C. 3233; Department of Commerce Delegation Order 10–4.

§ 301.6 [Removed and Reserved]

- 2. Remove and reserve § 301.6.

Dated: June 27, 2025.

Benjamin Page,

Deputy Assistant Secretary and Chief Operating Officer.

[FR Doc. 2025–12312 Filed 7–1–25; 8:45 am]

BILLING CODE 3510–24–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2025–1117; Project Identifier MCAI–2025–00845–R; Amendment 39–23072; AD 2025–13–06]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Helicopters Deutschland GmbH Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, EC135T3, and EC635T2+ helicopters. This AD was prompted by a report of a loss of the tail rotor controls due to a broken control rod of the yaw actuator. This AD requires visual inspection of the ball pivot, fluorescent penetrant inspection of the control rod, visual inspection and measurement of certain parts of the yaw actuator assembly, and depending on the results of these inspections, corrective actions. This AD also prohibits installing an affected part unless it is a serviceable part and certain requirements are met. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 18, 2025.

The Director of the Federal Register approved the incorporation by reference

of a certain publication listed in this AD as of July 18, 2025.

The FAA must receive comments on this AD by August 18, 2025.

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–2025–1117; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone +49 221 8999 000; email: *ADs@easa.europa.eu*; website: *easa.europa.eu*. You may find the EASA material on the EASA website at *ad.easa.europa.eu*. It is also available at *regulations.gov* under Docket No. FAA–2025–1117.

- You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Parkway, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT:

Steven Warwick, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY; phone: (817) 222–5225; email: *steven.r.warwick@faa.gov*.

SUPPLEMENTARY INFORMATION:**Comments Invited**

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments using a method listed under the **ADDRESSES** section. Include “Docket No. FAA–2025–1117; Project Identifier MCAI–2025–00845–R” at the beginning of your comments. The most helpful

comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Steven Warwick, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY. 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 2025–0108, dated May 8, 2025 (EASA AD 2025–0108) (also referred to as the MCAI) to correct an unsafe condition on Airbus Helicopters Deutschland GmbH Model EC135 P1, EC135 P2, EC135 P2+, EC135 P3, EC135 T1, EC135 T2, EC135 T2+, EC135 T3, EC635 P2+, EC635 P3, EC635 T1, EC635 T2+, and EC635 T3 helicopters.

The MCAI states an occurrence was reported where the pilot lost the tail rotor controls after hearing a noise from the rear of the helicopter, and further investigation identified a broken control rod of the yaw actuator. The MCAI also states the investigation to identify the root cause of the event is ongoing, and Airbus Helicopters Deutschland GmbH

is collecting fleet data to support the investigation. According to the MCAI, the unsafe condition, if not addressed, could lead to loss of control of the helicopter.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2025–1117.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2025–0108, which specifies procedures for visual inspection of ball pivot part-number (P/N) 92–201–00 and P/N 92–207–00; and yaw actuator assembly P/N L672M2005104, P/N L672M2005105, and P/N L672M2005106; and fluorescent penetrant inspection of control rod P/N L672M2006101 and P/N L672M2006102 and, depending on the inspection results, corrective actions to include the replacement of affected parts. EASA AD 2025–0108 also specifies procedures for measuring several dimensions and reporting the measurement results. Additionally, EASA AD 2025–0108 requires reporting the inspection results (including no findings) to AHD [Airbus Helicopters Deutschland]. EASA AD 2025–0108 prohibits installing certain parts on any helicopter unless certain requirements are met. EASA considers its AD an interim action and further action may follow.

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

FAA’s Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with 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 AD after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

AD Requirements

This AD requires accomplishing the actions specified in EASA AD 2025–0108, described previously, as incorporated by reference, except for

any differences identified as exceptions in the regulatory text of this AD. See “Differences Between this AD and the MCAI” for a discussion of the general differences included in this 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, EASA AD 2025–0108 is incorporated by reference in this AD. This AD requires compliance with EASA AD 2025–0108 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2025–0108 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 2025–0108. Material required by EASA AD 2025–0108 for compliance will be available at *regulations.gov* under Docket No. FAA–2025–1117 after this AD is published.

Differences Between This AD and the Referenced Material

The MCAI applies to Model EC635 P2+, EC635 P3, EC635 T1, and EC635 T3 helicopters, whereas this AD does not because those models do not have an FAA type certificate.

Interim Action

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

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are

“impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because tail rotor controls are critical components to maintaining controlled flight. Damage to the ball bearing control system could result in loss of tail rotor controls and consequent loss of control of the helicopter. The FAA has no information pertaining to the root cause, the extent of the root cause that may currently exist in helicopters, or how quickly the root cause may propagate to failure. Additionally, the compliance time in this AD for the required actions is within 50 hours time-in-service or 90 days, whichever occurs first, which is shorter than the time necessary for the public to comment and for publication of the final rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b).

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

Regulatory Flexibility Act

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

Costs of Compliance

The FAA estimates that this AD affects 318 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS				
Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect ball pivot and control rod	2 work-hours × \$85 per hour = \$170 ...	\$0	\$170	\$54,060

ESTIMATED COSTS—Continued

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Perform fluorescent penetrant inspection	2 work-hours × \$85 per hour = \$170 ...	0	170	54,060
Inspect and measure yaw actuator interface connections ..	2 work-hours × \$85 per hour = \$170 ...	0	170	54,060
Report inspection results	1 work-hour × \$85 per hour = \$85	0	85	27,030

The FAA estimates the following costs to do any necessary replacements that would be required based on the

results of the inspection. The agency has no way of determining the number of

helicopters that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace adapter	1 work-hour × \$85 per hour = \$85	\$803	\$888
Replace ball pivot	1 work-hour × \$85 per hour = \$85	2,846	2,931
Replace close tolerance bolt	1 work-hour × \$85 per hour = \$85	42	127
Replace connector cover	1 work-hour × \$85 per hour = \$85	571	656
Replace control rod	1 work-hour × \$85 per hour = \$85	6,835	6,920
Replace input lever	2 work-hours × \$85 per hour = \$170	9,755	9,925
Replace rod end	1 work-hour × \$85 per hour = \$85	643	728

Paperwork Reduction Act

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

- (1) Is not a "significant regulatory action" under Executive Order 12866, and
- (2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

Accordingly, under the authority delegated to me by the Administrator,

the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2025-13-06 Airbus Helicopters

Deutschland GmbH: Amendment 39-23072; Docket No. FAA-2025-1117; Project Identifier MCAI-2025-00845-R.

(a) Effective Date

This airworthiness directive (AD) is effective July 18, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Deutschland GmbH Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, EC135T3, and EC635T2+ helicopters, serial numbers 0001 through 1999 inclusive, certificated in any category.

Note 1 to paragraph (c): Helicopters with an EC135P3H designation are Model EC135P3 helicopters, and helicopters with an EC135T3H designation are Model EC135T3 helicopters.

(d) Subject

Joint Aircraft System Component (JASC) Code 6720, Tail Rotor Control System.

(e) Unsafe Condition

This AD was prompted by a report of a loss of tail rotor controls due to a broken control rod of the yaw actuator. The root cause of this damage is unknown, and investigation is ongoing. The FAA is issuing this AD to detect and address damage to the ball bearing control system. The unsafe condition, if not addressed, could result in loss of tail rotor controls and consequent loss of control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency AD 2025–0108, dated May 8, 2025 (EASA AD 2025–0108).

(h) Exceptions to EASA AD 2025–0108

(1) Where EASA AD 2025–0108 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(2) Where EASA AD 2025–0108 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where paragraph (2) of EASA AD 2025–0108 specifies “any discrepancy, as defined in the ASB”, this AD requires replacing that text with “any wear or damage.”

(4) Where the material referenced in EASA AD 2025–0108 specifies to examine the close-tolerance bolt, the input lever, the rod end, the adapter, and the connector cover for wear and damage, for the purposes of this AD damage is defined as specified in paragraphs (h)(4)(i) through (iv) of this AD, as applicable.

(i) Damage for the close-tolerance bolt is defined as deformed or stripped, rounded head; bent, stripped, or missing threads; bent shank; grooves in the shank, corrosion or rust; and gouges.

(ii) Damage for the input lever is defined as deformation or elongated attachment hole; bent flange; gouges; corrosion; and cracks.

(iii) Damage for the rod end is defined as corrosion, gouges, bending, and seizing.

(iv) Damage for the adapter or connector is defined as deformation, elongated attachment holes, gouges, cracks, corrosion, and missing surface coating on the adapter or connector.

(5) Where the material referenced in EASA AD 2025–0108 specifies if the ball pivot shows rough stiffness, hard stops, corrosion, or damage, for the purposes of this AD damage is defined as deformation (bent flanges), gouges, areas of bare metal, or missing finish.

(6) Where paragraph (4) of EASA AD 2025–0108 specifies to report inspection results to Airbus Helicopters Deutschland within certain compliance times, for this AD, report inspection results at the applicable times specified in paragraphs (h)(6)(i) or (ii) of this AD.

(i) For an inspection done on or after the effective date of this AD: Submit the report within 15 days after the inspection.

(ii) For an inspection done before the effective date of this AD: Submit the report

within 15 days after the effective date of this AD.

(7) Where the material referenced in EASA AD 2025–0108 specifies actions for non-installed equipment or parts, this AD does not require those actions.

(8) Where the material referenced in EASA AD 2025–0108 specifies to replace an affected part, this AD requires removing an affected part from service and replacing it with a serviceable part.

(9) This AD does not adopt the Remarks section of EASA AD 2025–0108.

(i) No Returning Parts Requirement

Although the material referenced in EASA AD 2025–0108 specifies to return parts to the manufacturer, this AD does not require that action.

(j) Special Flight Permits

Special flight permits are prohibited.

(k) Alternative Methods of Compliance (AMOCs)

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

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

(l) Additional information

For more information about this AD, contact Steven Warwick, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY; phone: (817) 222–5225; email: steven.r.warwick@faa.gov.

(m) 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 the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2025–0108, dated May 8, 2025.

(ii) [Reserved]

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

(4) You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Parkway, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this 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-locations or email fr.inspection@nara.gov.

Issued on June 18, 2025.

Steven W. Thompson,

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

[FR Doc. 2025–12388 Filed 6–30–25; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2025–0209; Project Identifier MCAI–2024–00636–E; Amendment 39–23073; AD 2025–13–07]

RIN 2120–AA64

Airworthiness Directives; Safran Helicopter Engines, S.A. (Type Certificate Previously Held by Turbomeca, S.A.) Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Safran Helicopter Engines, S.A. (Safran) Model ARRIUS 2B2 engines. This AD was prompted by a manufacturer review of collected data from in-service engines that indicated the preference injector may clog over time caused by fuel coking, which decreases the permeability of the preference injector. This AD requires initial and repetitive non-extinguishing tests for engine flameout and replacement of the preference injector if necessary, a one-time modification (software upgrade) of the electronic engine control unit (EECU) and, for certain engines, repetitive replacements of the preference injector. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 6, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 6, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2025–0209; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and

other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

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

- You may view this material at the FAA, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222-5110. It is also available at regulations.gov under Docket No. FAA-2025-0209.

FOR FURTHER INFORMATION CONTACT:

David Bergeron, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (860) 386-1805; email: david.j.bergeron@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Safran Helicopter Engines, S.A. (Safran) Model ARRIUS 2B2 engines. The NPRM was published in the **Federal Register** on February 25, 2025 (90 FR 10617). The NPRM was prompted by EASA AD 2024-0195R1, dated October 22, 2024 (EASA AD 2024-0195R1) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union, which revised EASA AD 2024-0195, dated October 18, 2024 (EASA AD 2024-0195). EASA AD 2024-0195 states that a manufacturer review of collected data from in-service engines indicated that the preference injector may clog over time caused by fuel coking, which could decrease the

permeability of the preference injector. EASA AD 2024-0195 also specifies non-extinguishing tests and replacements of the preference injector at reduced intervals, and upgrade of the EECU software based on two manufacturer design changes which, in combination, reduce the clogging rate, but do not mitigate the potential of the unsafe condition. The manufacturer also issued service material that provided instructions for a non-extinguishing test and replacement of the preference injector at shorter intervals than specified in the Engine Maintenance Manual. The manufacturer then developed an EECU software upgrade (modification TU 173) for certain engines installed on certain helicopters, which allows automatic accomplishment of the non-extinguishing test, and published service material providing instructions to embody the software upgrade on in-service engines.

EASA AD 2024-0195R1 states that EASA revised EASA AD 2024-0195 and issued EASA AD 2024-0195R1 to retain all actions from EASA AD 2024-0195 and amend the applicable groups, because modification TU 173 is applicable only to engines installed on Airbus Helicopters Deutschland EC135T2, EC135T2+, EC635T2, or EC635T2+ helicopters.

In the NPRM, the FAA proposed to require initial and repetitive non-extinguishing tests for engine flameout and replacement of the preference injector if necessary, a one-time modification (software upgrade) of the EECU and, for certain engines, repetitive replacements of the preference injector.

Clogging of the preference injector, if not detected and corrected, and if combined with a sharp reduction in the fuel flow during the flight after a pilot command, could lead to a flameout in the combustion chamber, which could result in an uncommanded in-flight shutdown of the engine and reduced control of the helicopter. The FAA is issuing 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-2025-0209.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from 1 individual commenter. The commenter supported the NPRM without change.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024-0195R1, which specifies procedures for initial and repetitive non-extinguishing tests, a one-time modification (software upgrade) of the EECU, and repetitive replacements of the preference injector. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 186 engines installed on helicopters of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Initial non-extinguishing test (186 engines)	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$15,810
Repetitive non-extinguishing test (54 engines)	1 work-hour × \$85 per hour = \$85	0	85	4,590
Injector replacement (186 engines)	1 work-hour × \$85 per hour = \$85	1,819	1,904	354,144
EECU software upgrade (132 engines)	7 work-hours × \$85 per hour = \$595	0	595	78,540

The FAA estimates the following costs to do any necessary on-condition replacement that would be required

based on the results of any required tests. The agency has no way of determining the number of engines that

might need this on-condition replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Injector replacement	1 work-hour x \$85 per hour = \$85	\$1,819	\$1,904

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2025–13–07 Safran Helicopter Engines, S.A. (Type Certificate previously held by Turbomeca, S.A.): Amendment 39–23073; Docket No. FAA–2025–0209; Project Identifier MCAI–2024–00636–E.

(a) Effective Date

This airworthiness directive (AD) is effective August 6, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Safran Helicopter Engines, S.A. (type certificate previously held by Turbomeca, S.A.) Model ARRIUS 2B2 engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7300, Engine Fuel and Control.

(e) Unsafe Condition

This AD was prompted by a manufacturer review of collected data from in-service engines that indicated the preference injector may clog over time caused by fuel coking, which could decrease the permeability of the preference injector. The FAA is issuing this AD to detect and correct clogging and decreased permeability of the preference injector due to fuel coking. The unsafe condition, if not addressed, when combined with a sharp reduction in fuel flow, could result in a flameout in the combustion chamber, which could result in an uncommanded in-flight shutdown of the engine and reduced control of the helicopter.

(f) Compliance

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

(g) Required Actions

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, European Union Aviation Safety Agency (EASA) AD 2024–0195R1, dated October 22, 2024 (EASA AD 2024–0195R1).

(h) Exceptions to EASA AD 2024–0195R1

(1) Where EASA AD 2024–0195R1 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the “Remarks” section of EASA AD 2024–0195R1.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2024–0195R1 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Additional Information

For more information about this AD, contact David Bergeron, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (860) 386–1805; email: david.j.bergeron@faa.gov.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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 the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0195R1, dated October 22, 2024.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADS@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, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(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-locations or email fr.inspection@nara.gov.

Issued on June 18, 2025.

Steven W. Thompson,

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

[FR Doc. 2025–12332 Filed 7–1–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–1116; Project Identifier MCAI–2024–00708–R; Amendment 39–23071; AD 2025–13–05]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Helicopters Model H160–B helicopters. This AD was prompted by occurrences of premature in-service degradation of the main rotor swashplate assembly (swashplate) bearing. This AD requires repetitively inspecting the swashplate bearing for the presence of grease, and depending on the inspection results, performing corrective actions. This AD requires performing certain operational checks, downloading and analyzing certain data, and, depending on the results of the operational checks, further corrective actions. This AD also requires repetitively performing one flight under specific conditions. Additionally, this AD requires inspecting grease on the swashplate bearing and, depending on the inspection results, applying a certain grease or replacing the grease. This AD allows installing certain part-numbered swashplate bearings provided certain requirements are met. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 17, 2025.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of July 17, 2025.

The FAA must receive comments on this AD by August 18, 2025.

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](https://www.regulations.gov). Follow the instructions for submitting comments.

- **Fax:** (202) 493–2251.

- **Mail:** U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- **Hand Delivery:** Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–1116; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone +49 221 8999 000; email: ADs@easa.europa.eu; website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–1116.

- You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Parkway, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT:

Aryanna Sanchez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (817) 222–4058; email: aryanna.t.sanchez@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA–2025–1116; Project Identifier MCAI–2024–00708–R” at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Aryanna Sanchez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590. 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 2024–0229, dated December 2, 2024 (EASA AD 2024–0229) (also referred to as the MCAI) to correct an unsafe condition on Airbus Helicopters Model H160–B helicopters. The MCAI states multiple occurrences were reported of premature in-service degradation of the swashplate bearing, which could have been due to the use of the wrong grease or a mixture of incompatible greases. The MCAI also states the health usage monitoring system (HUMS) has been effective to detect early degradation of the swashplate bearings; however, data shows that additional inspections and repetitive flights are needed to ensure HUMS data is analyzed on a regular basis to detect the degradation.

The FAA is issuing this AD to prevent premature swashplate bearing degradation. The unsafe condition, if not addressed, could result in failure of the swashplate bearing and consequent reduced control of the helicopter.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–1116.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0229, which specifies procedures for:

- repetitively inspecting the swashplate assembly and surrounding areas for the presence of black grease, and if abnormal grease is detected, performing corrective actions. Corrective actions include performing a functional test of the swashplate bearing and, depending on the results, replacing the main rotor mast assembly or repeating the functional tests.

- performing a check of the HUMS flight report and a check of the condition of the HUMS vibration overlimit monitoring operation, including downloading and analyzing the HUMS data of the swashplate bearing. If a discrepancy is detected, the MCAI specifies to contact AH [Airbus Helicopters] for corrective actions.

- repetitively performing one flight under specific conditions to verify the status of the HUMS vibration overlimit monitoring.

- identifying the type of grease that was applied during the last swashplate bearing lubrication and if incorrect grease was applied or if the grease is unknown, replacing it.

EASA AD 2024–0229 allows an affected swashplate bearing to be installed on a helicopter provided the swashplate bearing is new and has not previously been installed on a helicopter.

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

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with 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 AD after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

AD Requirements

This AD requires accomplishing the actions specified in EASA AD 2024–0229, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD. See “Differences Between this AD and the MCAI” for a discussion of the general

differences included in this AD. The owner/operator (pilot) holding at least a private pilot certificate may perform the initial check of the HUMS flight report or repetitively perform one flight to verify the status of the HUMS vibration overlimit monitoring and must enter compliance with the applicable paragraph(s) of the AD into the helicopter maintenance records in accordance with 14 CFR 43.9(a) and 91.417(a)(2)(v). The pilot may perform these actions because they only involve visually checking the HUMS flight report or performing a flight. These actions could be performed equally well by a pilot or a mechanic. This is an exception to the FAA's standard maintenance regulations.

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, EASA AD 2024–0229 is incorporated by reference in this AD. This AD requires compliance with EASA AD 2024–0229 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0229 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 2024–0229. Material required by EASA AD 2024–0229 for compliance will be available at regulations.gov under Docket No. FAA–2025–1116 after this AD is published.

Differences Between This AD and the MCAI

Where the MCAI does not specify who is authorized to download and analyze the HUMS vibration overlimit checks, this AD requires those actions to be accomplished by persons authorized under 14 CFR 43.3.

Where the MCAI requires accomplishing corrective actions in accordance with the instructions of the service material, and within the compliance times specified in the service material referenced in the MCAI, this AD requires accomplishing the

instructions or corrective actions in accordance with a method approved by the FAA, EASA; or Airbus Helicopters' EASA Design Organization Approval (DOA).

Where material referenced in the MCAI does not specify who may perform a functional test or who may perform the dedicated maintenance instructions for any other exceedance, this AD does not allow those procedures to be performed by a pilot (owner/operator) and requires those procedures to be accomplished by persons authorized under 14 CFR 43.3.

Where the material referenced in the MCAI allows “operations and maintenance” to analyze a flight report, perform a check of the HUMS vibration overlimit monitoring operation, download and transfer HUMS data to Airbus Helicopters, and perform one flight to verify the status of the HUMS vibration overlimit monitoring, this AD only allows a pilot to perform the initial check of the HUMS flight report for the presence of a reported event and to repetitively perform one flight to verify the status of the HUMS vibration overlimit monitoring.

Interim Action

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

Justification for Immediate Adoption and Determination of the Effective Date

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

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because several occurrences have already been reported of in-service degradation on these swashplate bearings, which are critical to the control of the helicopter. Additionally, the cause of the unsafe condition is still being investigated and the reporting requirements may be crucial to

understanding the root cause. In light of this, the initial action required by this AD must be accomplished before further flight or within 15 hours time-in-service for some helicopters, which is shorter than the time necessary for the public to comment and for publication of the final rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b).

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

Regulatory Flexibility Act

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

Costs of Compliance

The FAA estimates that this AD affects nine helicopters of U.S. registry. Labor costs are estimated at \$85 per hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Visually inspecting for the presence of black grease will take 0.5 work-hours for an estimated cost of \$43 per helicopter and \$387 for the U.S. fleet.

Accomplishing a check of the HUMS vibration overlimit monitoring will take 0.25 work-hours for an estimated cost of \$21 per helicopter and \$189 for the U.S. fleet.

Downloading and sending the HUMS data to Airbus Helicopters for analysis, which is considered a reporting requirement in this AD, will take 1 work-hour for an estimated cost of \$85 per helicopter and \$765 for the U.S. fleet.

Verifying helicopter records to determine which grease was applied will take 0.25 work-hours for an estimated cost of \$21 per helicopter and \$189 for the U.S. fleet.

If required, removing and replacing grease will take 5 work-hours for an estimated cost of \$425 per helicopter.

If required, accomplishing a functional test will take 1 work-hour for an estimated cost of \$85 per helicopter.

If required, replacing an affected main rotor mast will take 114 work-hours and parts will cost up to \$316,023 for an estimated cost of \$325,713 per helicopter.

The FAA has no way of determining the number of work-hours it will take to accomplish the corrective actions if HUMS support is needed.

Paperwork Reduction Act

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

responsibilities among the various levels of government.

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

- (1) Is not a "significant regulatory action" under Executive Order 12866, and
- (2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2025-13-05 Airbus Helicopters:

Amendment 39-23071; Docket No. FAA-2025-1116; Project Identifier MCAI-2024-00708-R.

(a) Effective Date

This airworthiness directive (AD) is effective July 17, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Model H160-B helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code: 6230, Main rotor mast/swashplate.

(e) Unsafe Condition

This AD was prompted by reports of premature degradation of the main rotor swashplate assembly (swashplate) bearing. The FAA is issuing this AD to prevent premature swashplate bearing degradation. The unsafe condition, if not addressed, could result in failure of the swashplate bearing and consequent reduced control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in

accordance with, European Union Aviation Safety Agency AD 2024–0229, dated December 2, 2024 (EASA AD 2024–0229).

(h) Exceptions to EASA AD 2024–0229

(1) Where EASA AD 2024–0229 requires compliance in terms of flight hours, this AD requires using hours time-in-service (TIS).

(2) Where EASA AD 2024–0229 refers to its effective date or where EASA AD 2024–0229 refers to December 25, 2023 [the effective date of EASA AD 2023–0222–E], this AD requires using the effective date of this AD.

(3) Where paragraph (1) of EASA AD 2024–0229 specifies “Within 15 flight hours (FH) or before the next cleaning of the swashplate bearing, whichever occurs first after December 25, 2023 [the effective date of EASA AD 2023–0222–E], and, thereafter, before any cleaning of the swashplate bearings or at intervals not exceeding 15 flight hours [FH], whichever occurs first”, this AD requires replacing that text with “Within 15 hours TIS or at the next 50 hour Swashplate Bearing—Functional Test or 300 hour Swashplate Bearing—Lubrication, whichever occurs first after July 17, 2025, the effective date of FAA AD 2025–13–05, and thereafter at intervals not to exceed 15 hours TIS”.

(4) Where the material referenced in paragraph (3) of EASA AD 2024–0229 specifies a check of the Health Usage Monitoring System (HUMS) flight report for reporting of MR SWASHPLATE: EXCEEDANCE in accordance with paragraph 4.3 of the accomplishment procedure of the ASB [Alert Service Bulletin], for this AD, the owner/operator (pilot) holding at least a private pilot certificate may perform only the initial check of the HUMS flight report for the presence of a reported event and must enter compliance into the helicopter maintenance records in accordance with 14 CFR 43.9(a) and 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

Note 1 to paragraph (h)(4): The initial check of the HUMS flight report is part of the normal flight report procedures, and the flowcharts are not required to perform the initial check.

(5) Where paragraph (4) of EASA AD 2024–0229 specifies a check of the HUMS vibration overlimit monitoring for reporting of MR SWASHPLATE: UNDEFINED or MR SWASHPLATE: EXCEEDANCE in accordance with the instructions of paragraph 4.4 of the accomplishment procedure of the ASB, this AD requires those actions be accomplished by persons authorized under 14 CFR 43.3 and may not be performed by the owner/operator (pilot) holding at least a private pilot certificate.

(6) Where paragraph (6) of EASA AD 2024–0229 specifies “perform one flight to verify the status of the HUMS vibration overlimit monitoring in accordance with the instructions of paragraph 4.6 of the accomplishment procedure of the ASB”, this AD requires replacing that text with “perform one flight to verify the status of the HUMS vibration overlimit monitoring. The owner/operator (pilot) may perform this flight and verification and must enter compliance with this paragraph into the helicopter

maintenance records in accordance with 14 CFR 43.9(a) and 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439”.

(7) Where paragraph (7) of EASA AD 2024–0229 specifies “Where the ASB provides instruction to contact AH [Airbus Helicopters] HUMS support, this AD requires to contact AH for applicable instructions and to accomplish those instructions accordingly”, this AD requires replacing that text with “Accomplish the instructions or corrective actions in accordance with a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus Helicopters’ EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature”.

(8) Where paragraph (8) of EASA AD 2024–0229 specifies “check”, this AD requires replacing that text with “test”.

(9) Where paragraph (8) of EASA AD 2024–0229 refers to any discrepancy, for the purposes of this AD, a discrepancy (pertaining to any functional test [check]) is identified as any abnormal relief or hard point (ratcheting or blocking) felt during rotation at a low constant speed, or any axial play on the installed rotating swashplate. An abnormal relief occurs when the passage of the balls on a spalling of the race can be felt by vibrations in the hands and arms during the rotation. A hard point occurs when there is a ratcheting or blocking of the ball bearing and is felt by a sensation of braking or stopping exerting an additional force during the rotation. Axial play is detected by manually shaking the equipped rotating swashplate vertically from top to bottom (up and down).

Note 2 to paragraph (h)(9): Additional information to identify discrepancies is included in the video specified in Work Card Swashplate Bearing—Functional test 62–32–3001, 340, dated November 4, 2022.

(10) Where paragraph (8) of EASA AD 2024–0229 specifies “replace the main rotor mast assembly in accordance with the instructions of the ASB”, this AD requires replacing that text with “remove the main rotor mast assembly from service in accordance with the instructions of the ASB and replace it with an airworthy main rotor mast assembly”.

(11) Instead of complying with paragraph (10) of EASA AD 2024–0229, for this AD, as of the effective date of this AD, do not lubricate the swashplate bearing with unknown grease or any grease other than Nycogrease GN10.

(12) Where paragraph (11) of EASA AD 2024–0229 specifies “Before next swashplate bearings lubrication or within 15 FH whichever occurs first after 25 December 2023 [the effective date of EASA AD 2023–0222–E],”, this AD requires replacing that text with “Within 15 hours TIS or at the next 300 hour Swashplate Bearing—Lubrication, whichever occurs first, after the effective date of AD 2025–13–05”.

(13) Where paragraph (12) of EASA AD 2024–0229 specifies “it is determined that the grease used during the last swashplate bearings lubrication is not listed in CM115 type 1, or it is unknown”, this AD requires

replacing that text with “unknown grease or any grease other than Nycogrease GN10 was used”.

(14) Where paragraph (14) of EASA AD 2024–0229 specifies “Inspection, corrective actions, and greasing accomplished on a helicopter before the effective date of this AD in accordance with the instructions of ASB H160–B 62–32–0001 Issue 001 are acceptable for compliance with the requirements of paragraphs (1) to (5), and (7) to (12) of this AD, as applicable, for that helicopter”, this AD requires replacing that text with “Initial inspection, corrective actions, and greasing accomplished on a helicopter before the effective date of AD 2025–13–05 in accordance with the instructions of ASB H160–B 62–32–0001 Issue 001, dated December 19, 2023, are acceptable for compliance with the requirements of paragraphs (1) through (5), and (7) through (12) of EASA AD 2024–0229, as applicable, for that helicopter”.

(15) This AD does not adopt the Remarks section of EASA AD 2024–0229.

(i) Alternative Methods of Compliance (AMOCs)

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

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

(j) Additional Information

(1) For more information about this AD, contact Aryanna Sanchez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (817) 222–4058; email: aryanna.t.sanchez@faa.gov.

(2) Airbus Helicopters material identified in this AD that is not incorporated by reference is available at Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone: (972) 641–0000 or (800) 232–0323; fax: (972) 641–3775; or at airbus.com/en/products-services/helicopters/hcare-services/airbusworld.

(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 the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0229, dated December 2, 2024.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADS@easa.europa.eu;

website: easa.europa.eu. You may find the EASA material on the EASA website at [ad.easa.europa.eu](https://easa.europa.eu).

(4) You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Parkway, Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

(5) You may view this 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-locations or email fr.inspection@nara.gov.

Issued on June 27, 2025.

Steven W. Thompson,

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

[FR Doc. 2025-12377 Filed 6-30-25; 4:15 pm]

BILLING CODE 4910-13-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 40

[Docket No. RM24-7-000; Order No. 907]

Critical Infrastructure Protection Reliability Standard CIP-015-1—Cyber Security—Internal Network Security Monitoring

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final action.

SUMMARY: The Federal Energy Regulatory Commission (Commission) approves proposed Reliability Standard CIP-015-1 (Cyber Security—Internal Network Security Monitoring), which the North American Electric Reliability Corporation (NERC), submitted in response to a Commission directive. In addition, the Commission directs NERC to develop certain modifications to proposed Reliability Standard CIP-015-1 to extend internal network security monitoring to include electronic access control or monitoring systems and physical access control systems outside of the electronic security perimeter. The Commission also provides greater clarity about the term CIP-networked environment as it is used in proposed Reliability Standard CIP-015-1.

DATES: This action is effective September 2, 2025.

FOR FURTHER INFORMATION CONTACT: Margaret Steiner (Technical

Information), Office of Electric Reliability, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502-6704. Margaret.Steiner@ferc.gov

Hampden T. Macbeth (Legal Information), Office of General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502-8957. Hampden.Macbeth@ferc.gov

SUPPLEMENTARY INFORMATION:

1. Pursuant to section 215(d)(2) of the Federal Power Act (FPA),¹ the Commission approves proposed Critical Infrastructure Protection (CIP) Reliability Standard CIP-015-1 (Cyber Security—Internal Network Security Monitoring). The North American Electric Reliability Corporation (NERC), the Commission-certified Electric Reliability Organization (ERO), submitted proposed Reliability Standard CIP-015-1 for Commission approval in response to a Commission directive in Order No. 887.² In Order No. 887, the Commission directed that NERC develop new or modified CIP Reliability Standards that require internal network security monitoring (INSM)³ for the CIP-networked environment for all high impact bulk electric system (BES) Cyber Systems⁴ with and without external routable connectivity⁵ and medium impact BES Cyber Systems with external routable connectivity.⁶

2. Consistent with Order No. 887, Reliability Standard CIP-015-1 improves upon the currently effective CIP Reliability Standards by establishing requirements for INSM for network traffic inside an electronic security perimeter. Reliability Standard CIP-015-1 requires INSM for all high impact BES Cyber Systems with and without external routable connectivity and medium impact BES Cyber Systems with external routable connectivity to ensure the identification of anomalous

¹ 16 U.S.C. 824o(d)(2).

² *Internal Network Sec. Monitoring for High & Medium Impact Bulk Elec. Sys. Cyber Sys.*, Order No. 887, 88 FR 8354 (Feb. 9, 2023), 182 FERC ¶ 61,021 (2023).

³ INSM is a subset of network security monitoring that is applied within a trust zone, such as a perimeter zone with elevated credentials inside of an entity's internal network.

⁴ NERC defines BES Cyber Systems as “One or more BES Cyber Assets logically grouped by a responsible entity to perform one or more reliability tasks for a functional entity.” See NERC, *Glossary of Terms Used in NERC Reliability Standards*, (February 26, 2025), https://www.nerc.com/pa/Stand/Glossary%20of%20Terms/Glossary_of_Terms.pdf (NERC Glossary). BES Cyber Systems are categorized as high, medium, or low impact depending on the functions of the assets housed within each system and the risk they potentially pose to the reliable operation of the Bulk-Power System. Reliability Standard CIP-002-1a (BES Cyber System Categorization).

⁵ External routable connectivity is “[t]he ability to access a BES Cyber System from a Cyber Asset that is outside of its associated Electronic Security Perimeter via a bi-directional routable protocol connection.” NERC Glossary.

⁶ Order No. 887, 182 FERC ¶ 61,021 at P 49.

network activity indicating an ongoing attack.⁷ Accordingly, the Commission approves Reliability Standard CIP-015-1 as it is largely responsive to the Commission's directives in Order No. 887 and will improve the security posture of the Bulk-Power System. We also approve the associated violation risk factors and violation severity levels, implementation plan, and effective date.

3. In Order No. 887, the Commission used the term CIP-networked environment to define the “trust zone” in which INSM requirements should apply.⁸ The Commission, however, did not define the term CIP-networked environment in Order No. 887. Nor did NERC propose a definition in its petition. Rather, NERC and other commenters ask in Notice of Proposed Rulemaking (NOPR) comments that the Commission clarify the meaning of the term CIP-networked environment.⁹

4. We clarify that the term CIP-networked environment does not cover all of a responsible entity's network. The CIP-networked environment includes traffic inside an electronic security perimeter but also extends beyond the perimeter. The CIP-networked environment includes the systems within the electronic security perimeter *and* network connections among and between electronic access control or monitoring systems (EACMS)¹⁰ and physical access control systems (PACS)¹¹ external to the electronic security perimeter as discussed in greater detail below.¹² It is necessary to defend against attacks external to the electronic security perimeter because they may compromise systems such as EACMS and PACS, and then infiltrate the perimeter as a trusted communication. Thus, EACMS and PACS are included in the CIP-networked environment.

5. With this clarification, it is apparent that Reliability Standard CIP-015-1, which requires INSM only within the electronic security perimeter,

⁷ NERC Petition at 1, 13.

⁸ E.g., Order No. 887, 182 FERC ¶ 61,021 at P 2.

⁹ *Critical Infrastructure Protection Reliability Standard CIP-015-1—Cyber Security—Internal Network Security Monitoring*, 89 FR 79178 (Sept. 27, 2024), 188 FERC ¶ 61,175 (2024) (NOPR).

¹⁰ EACMS are “Cyber Assets that perform electronic access control or electronic access monitoring of the Electronic Security Perimeter(s) or BES Cyber Systems. This includes Intermediate Systems.” NERC Glossary.

¹¹ PACS are “Cyber Assets that control, alert, or log access to the Physical Security Perimeter(s), exclusive of locally mounted hardware or devices at the Physical Security Perimeter such as motion sensors, electronic lock control mechanisms, and badge readers.” *Id.*

¹² When we refer to EACMS and PACS in this final rule it also includes the network segments delineated in P 43, *infra*.

is not fully compliant with the Commission's directive in Order No. 887. Therefore, pursuant to section 215(d)(5) of the FPA,¹³ we direct NERC to develop further modifications to proposed Reliability Standard CIP-015-1, within 12 months of the effective date of the final rule in this proceeding, to extend INSM to include EACMS and PACS outside of the electronic security perimeter.

I. Background

A. Section 215 and Mandatory Reliability Standards

6. Section 215 of the FPA provides that the Commission may certify an ERO, the purpose of which is to develop mandatory and enforceable Reliability Standards, subject to Commission review and approval.¹⁴ Reliability Standards may be enforced by the ERO, subject to Commission oversight, or by the Commission independently.¹⁵ Pursuant to section 215 of the FPA, the Commission established a process to select and certify an ERO,¹⁶ and subsequently certified NERC.¹⁷

B. Internal Network Security Monitoring

7. INSM is a subset of network security monitoring that is applied within a trust zone,¹⁸ such as a perimeter zone with elevated credentials inside of an entity's internal network. For this final rule and Order No. 887, the trust zone applicable to INSM is the CIP-networked environment.¹⁹ INSM enables continuing visibility over communications between networked devices within a trust zone and detection of malicious activity that has circumvented perimeter controls.

Further, INSM facilitates the detection of anomalous network activity indicative of an attack in progress, thus increasing the probability of early detection and allowing for quicker mitigation and recovery from an attack.

8. INSM is designed to address as early as possible situations where perimeter network defenses are breached by detecting intrusions and malicious activity within a trust zone. INSM consists of three stages: (1) collection; (2) detection; and (3) analysis. Taken together, these three stages provide the benefit of early detection and alerting of intrusions and malicious activity.²⁰ INSM better positions an entity to detect an attacker in the early phases of an attack and reduces the likelihood that an attacker can gain a strong foothold, including operational control, on the target system. In addition to early detection and mitigation, INSM may improve incident response by providing higher quality data about the extent of an attack internal to a trust zone. Finally, INSM provides insight into east-west (*i.e.*, lateral) network traffic²¹ happening inside the network perimeter, which enables a more comprehensive picture of the extent of an attack compared to data gathered from the network perimeter alone.²²

C. Order No. 887

9. On January 19, 2023, in Order No. 887, the Commission issued a final rule that directed that NERC develop "new or modified CIP Reliability Standards requiring INSM for all high impact BES Cyber Systems with and without external routable connectivity and

medium impact BES Cyber Systems with external routable connectivity to ensure the detection of anomalous network activity indicative of an attack in progress."²³ The Commission, noting that INSM is "applied within a 'trust zone,' such as an electronic security perimeter," stated that for the final rule the applicable trust zone for INSM is the CIP-networked environment.²⁴

10. The Commission explained that the currently effective CIP Reliability Standards focus on preventing unauthorized access at the electronic security perimeter and do not require INSM inside the trusted CIP-networked environment.²⁵ The Commission determined that this left a reliability gap when vendors or individuals with authorized access are deemed trustworthy but could still introduce a cybersecurity risk.²⁶ The Commission then concluded that requirements to implement INSM will "fill a gap in the current suite of CIP Reliability Standards and improve the cybersecurity posture of the Bulk-Power System."²⁷

11. The Commission directed that NERC ensure that the new or modified CIP Reliability Standards address three security objectives for east-west network traffic. First, the new or modified CIP Reliability Standards should address the need for each responsible entity to develop a baseline for their network activity by analyzing for security purposes their network traffic and data flows. Second, the new or modified CIP Reliability Standards should address the need for responsible entities to monitor and detect "unauthorized activity, connections, devices, network communication protocols, and software" in the CIP-networked environment. Third, the new or modified CIP Reliability Standards

¹³ 16 U.S.C. 824o(d)(5).

¹⁴ *Id.* 824o(c).

¹⁵ *Id.* 824o(e).

¹⁶ *Rules Concerning Certification of the Elec. Reliability Org.; & Procs. for the Establishment, Approval, & Enf't of Elec. Reliability Standards*, Order No. 672, 71 FR 8662 (Feb. 17, 2006), 114 FERC ¶ 61,104, *order on reh'g*, Order No. 672-A, 71 FR 19814 (Apr. 18, 2006), 114 FERC ¶ 61,328 (2006); *see also* 18 CFR 39.4(b).

¹⁷ *N. Am. Elec. Reliability Corp.*, 116 FERC ¶ 61,062, *order on reh'g and compliance*, 117 FERC ¶ 61,126 (2006), *aff'd sub nom. Alcoa, Inc. v. FERC*, 564 F.3d 1342 (D.C. Cir. 2009).

¹⁸ The U.S. Department of Homeland Security, Cybersecurity and Infrastructure Security Agency (CISA) defines trust zone as a "discrete computing environment designated for information processing, storage, and/or transmission that share the rigor or robustness of the applicable security capabilities necessary to protect the traffic transiting in and out of a zone and/or the information within the zone." CISA, *Trusted Internet Connections 3.0: Reference Architecture*, 2 (July 2020), https://www.cisa.gov/sites/default/files/publications/CISA_TIC%203.0%20Vol.%20%20Reference%20Architecture.pdf.

¹⁹ Order No. 887, 182 FERC ¶ 61,021 at P 2.

²⁰ *See* Chris Sanders & Jason Smith, *Applied Network Security Monitoring*, 9–10 (2013); *see also* ISACA, *Applied Collection Framework: A Risk-Driven Approach to Cybersecurity Monitoring* (Aug. 18, 2020), <https://www.isaca.org/resources/news-and-trends/isaca-now-blog/2020/applied-collection-framework>.

²¹ East-west traffic refers to the communications among BES Cyber Systems and is the specific type of network traffic that remains within the network perimeter. It may refer to communication peer-to-peer industrial automation and control systems devices in a network or to activity between servers or networks inside a data center, rather than the data and applications that traverse networks to the outside world. CISCO, *Networking and Security in Industrial Automation Environments Design Guide*, 111 (Aug. 2020), https://www.cisco.com/c/en/us/td/docs/solutions/Verticals/Industrial_Automation/IA_Horizontal/DG/Industrial-AutomationDG.pdf; The President's National Security Telecommunications Advisory Committee, *Report to the President on Software-Defined Networking*, E-3 (Aug. 2020), <https://www.cisa.gov/sites/default/files/publications/NSTAC%20SDN%20Report%20%288-12-20%29.pdf>.

²² CISA, *CISA Analysis: FY2020 Risk and Vulnerability Assessments* (July 2021), https://www.cisa.gov/sites/default/files/publications/FY20-RVA-Analysis_508C.pdf.

²³ Order No. 887, 182 FERC ¶ 61,021 at P 3.

²⁴ *Id.* P 2.

²⁵ *Id.* P 20.

²⁶ *Id.* An attacker could move among devices inside a trust zone and perform actions such as: (1) escalate privileges (such as gaining administrator account privileges through a vulnerability); (2) move undetected inside the CIP-networked environment; or (3) execute a virus, ransomware, or another form of unauthorized code. *Id.* P 19.

²⁷ *Id.* P 49 (citing NERC Comments in Response to Notice of Proposed Rulemaking under Docket No. RM22-3-000 at 4-5 (current CIP Standards require "malicious communications monitoring at the Electronic Access Point on the [electronic security perimeter], not necessarily monitoring of activity of those who already have access to the network"). The Bulk-Power System is defined in the FPA as facilities and control systems necessary for operating an interconnected electric energy transmission network (or any portion thereof); and electric energy from generating facilities needed to maintain transmission system reliability. The term does not include facilities used in the local distribution of electric energy. 16 U.S.C. 824a(a)(1).

should provide responsible entities with flexibility in determining how to best identify anomalous activity with a high level of confidence, so long as the methods ensure: (1) logging of network traffic; (2) maintaining the logs, and other data collected, regarding network traffic that are of “sufficient data fidelity to draw meaningful conclusions” to investigate an incident; and (3) maintaining the integrity of the logs and other data by employing measures that minimize the likelihood of an attacker removing evidence of their tactics, techniques, and procedures.²⁸

D. NERC Petition and Proposed Reliability Standard CIP-015-1

12. On June 24, 2024, NERC submitted for Commission approval proposed Reliability Standard CIP-015-1 and the associated violation risk factors and violation severity levels, implementation plan, and effective date.²⁹ NERC stated that proposed Reliability Standard CIP-015-1 is intended to advance the reliability of the Bulk-Power System by providing a comprehensive suite of forward looking and objective-based requirements for INSM.³⁰

13. NERC explained that the proposed Reliability Standard would address the directives in Order No. 887 by establishing three requirements for responsible entities to implement INSM systems and processes:

- *Requirement R1:* responsible entities would be required to implement process(es) to monitor, detect, and evaluate anomalous activity in “networks protected by the Responsible Entity’s Electronic Security Perimeter(s)” of high impact BES Cyber Systems and medium impact BES Cyber Systems with external routable connectivity.³¹

- *Requirement R2:* responsible entities would be required to implement process(es) for retaining INSM data associated with anomalous network activity as determined by the applicable responsible entities.

- *Requirement R3:* responsible entities would be required to implement process(es) to protect INSM monitoring data collected and retained in support of Requirements R1 and R2 to guard against the risk of unauthorized deletion or modification.

14. According to NERC, Requirement R1 applies to data flows within “networks protected by the Responsible Entity’s Electronic Security Perimeter(s).”³² NERC stated that proposed Reliability Standard CIP-015-1’s scope is consistent with the plain language of Order No. 887, which stated that INSM should apply within a trust zone, “such as an electronic security perimeter,” and that the trust zone for INSM is the CIP-networked environment.³³ NERC stated that its approach would provide the greatest benefits to the reliability of the Bulk-Power System by focusing industry’s limited resources on the most critical environment, “networks protected by the Responsible Entity’s Electronic Security Perimeter.”³⁴

E. Notice of Proposed Rulemaking

15. On September 19, 2024, the Commission issued a NOPR proposing to approve proposed Reliability Standard CIP-015-1 as just, reasonable, not unduly discriminatory or preferential, and in the public interest.³⁵ The NOPR stated that the three requirements of the proposed Reliability Standard aligned with the security objectives identified in Order No. 887.³⁶

16. While proposing to approve proposed Reliability Standard CIP-015-1, the Commission also proposed to direct that NERC develop modifications to the Reliability Standard to address a reliability gap. Specifically, the Commission stated that proposed Reliability Standard CIP-015-1 does not fully implement the scope of protection contemplated in Order No. 887 because it limits INSM implementation to within the electronic security perimeter, instead of extending it to the entire CIP-networked environment.³⁷ To address this reliability gap, the Commission proposed to direct NERC to develop modifications to proposed Reliability Standard CIP-015-1 to include EACMS and PACS outside of the electronic security perimeter, thereby protecting the reliability and security of all trust zones of the CIP-networked environment.³⁸

17. In response to the NOPR, five entities submitted comments: ISO/RTO Council (IRC); New England States Committee on Electricity (NESCOE); NERC; OpenPolicy; and American Public Power Association, Edison

Electric Institute, Electric Power Supply Association, the Large Public Power Council, and the National Rural Electric Cooperative Association (collectively, Trade Associations). The discussion below addresses the proposals in the NOPR as well as the NOPR comments.

II. Discussion

18. Pursuant to section 215(d)(2) of the FPA, we approve proposed Reliability Standard CIP-015-1 as just, reasonable, not unduly discriminatory or preferential, and in the public interest. We find that proposed Reliability Standard CIP-015-1 improves the cybersecurity posture of the Bulk-Power System by requiring applicable entities to implement INSM to ensure the detection of anomalous network activity indicative of an attack in progress. The proposed Reliability Standard in main addresses the Commission’s directives in Order No. 887 and implements INSM by mandating the collection, detection, evaluation of, and appropriate response to anomalous activity for east-west network traffic.³⁹

19. While we approve proposed Reliability Standard CIP-015-1, we also determine that the Standard does not fully address the scope of INSM implementation as contemplated in Order No. 887. As discussed below, a reliability and security gap remains because the Standard does not require implementation of INSM for the entire CIP-networked environment, *i.e.*, outside the electronic security perimeter inclusive of EACMS and PACS. To address this gap, we direct NERC, pursuant to section 215(d)(5) of the FPA, to develop and file within 12 months of the effective date of this final rule modifications to Reliability Standard CIP-015-1 to extend INSM implementation to EACMS and PACS outside of the electronic security perimeter.

20. Below, we discuss the following: (A) proposed Reliability Standard CIP-015-1; (B) extending INSM to EACMS and PACS beyond the electronic security perimeter; and (C) the timeline to develop modifications to proposed Reliability Standard CIP-015-1.

A. Proposed Reliability Standard CIP-015-1

1. NOPR

21. In the NOPR, the Commission proposed to approve proposed Reliability Standard CIP-015-1 as just, reasonable, not unduly discriminatory

²⁸ Order No. 887, 182 FERC ¶ 61,021 at PP 79–80.

²⁹ NERC Petition at 2, 26–28. Proposed Reliability Standard CIP-015-1 is not attached to this final rule. The proposed Reliability Standard is available on the Commission’s eLibrary document retrieval system in Docket No. RM24-7-000 and on the NERC website, www.nerc.com.

³⁰ *Id.* at 4.

³¹ *Id.*, Ex. A (Proposed Reliability Standard CIP-015-1) at 6.

³² *Id.*

³³ *Id.* at 16 (quoting Order No. 887, 182 FERC ¶ 61,021 at P 2).

³⁴ *Id.* at 14, 17.

³⁵ NOPR, 188 FERC ¶ 61,175.

³⁶ *Id.* P 12.

³⁷ *Id.* P 14.

³⁸ *Id.*

³⁹ See P 11 *supra*; Order No. 887, 182 FERC ¶ 61,021 at PP 79–80.

or preferential, and in the public interest.

2. Comments

22. NERC, NESCOE, OpenPolicy, and Trade Associations support the Commission's proposal to approve proposed Reliability Standard CIP-015-1.⁴⁰ NERC, OpenPolicy, and Trade Associations indicate that proposed Reliability Standard CIP-015-1 would improve the detection of anomalous, malicious, or unauthorized network activity.⁴¹ NERC and OpenPolicy both note that improved detection of anomalous or malicious activity will strengthen responses to and recovery from threats and attacks.⁴² No commenters oppose approval of the proposed Reliability Standard.

23. NERC asserts that proposed Reliability Standard CIP-015-1 would strengthen the reliability of the Bulk-Power System by requiring INSM for all high impact BES Cyber Systems and medium impact BES Cyber Systems with external routable connectivity inside an electronic security perimeter.⁴³ According to NERC, the proposed Standard would further improve the cybersecurity posture of the Bulk-Power System by providing visibility into east-west communications within the electronic security perimeter.⁴⁴

24. NESCOE recommends that the Commission "take all necessary steps" to protect the security of the electric grid from malicious actors as new technologies with cybersecurity vulnerabilities are integrated into the grid.⁴⁵ Thus, NESCOE states that it supports the NOPR proposals, noting that the proposals are aimed at closing a reliability and security gap.

25. OpenPolicy, while supporting approval of proposed Reliability Standard CIP-015-1, also recommends ways to strengthen the proposed Standard. For example, OpenPolicy proposes adopting scalable and modular INSM architectures to adapt to evolving cybersecurity threats by enhancing threat detection and simplifying compliance processes; and mandating robust encryption standards to secure logs against tampering and unauthorized access.⁴⁶

⁴⁰ NERC Comments at 2; NESCOE Comments at 3; OpenPolicy Comments at 1; Trade Associations Comments at 2.

⁴¹ NERC Comments at 2; OpenPolicy Comments at 3; Trade Associations Comments at 2.

⁴² NERC Comments at 2; OpenPolicy Comments at 2.

⁴³ NERC Comments at 2.

⁴⁴ *Id.* at 3.

⁴⁵ NESCOE Comments at 2-3.

⁴⁶ OpenPolicy Comments at 2-4.

3. Commission Determination

26. Pursuant to section 215(d)(2) of the FPA, we adopt the NOPR proposal to approve proposed Reliability Standard CIP-015-1 as just, reasonable, not unduly discriminatory or preferential, and in the public interest.

27. We agree with NERC, OpenPolicy, and Trade Associations that proposed Reliability Standard CIP-015-1 will improve detection of anomalous, malicious, or unauthorized network activity, assisting responsible entities in responding to cyber attacks within the electronic security perimeter.⁴⁷ We determine that improved detection and response to cyber attacks and visibility into east-west communication—lacking in other CIP Reliability Standards—will improve the security posture of the electric industry, strengthening the reliability of the Bulk-Power System.⁴⁸ Further, we find that proposed Reliability Standard CIP-015-1 fulfills the directive in Order No. 887 to require responsible entities to implement INSM for all high impact BES Cyber Systems and medium impact BES Cyber Systems with external routable connectivity, albeit only within the electronic security perimeter. Additionally, proposed Reliability Standard CIP-015-1 satisfies the directive in Order No. 887 that the Reliability Standard address the three security objectives for east-west network traffic.

28. We decline to direct NERC to modify the proposed Standard to address OpenPolicy's recommendations. We note, however, that responsible entities, in addition to implementing the INSM requirements set forth in proposed Reliability Standard CIP-015-1, may voluntarily choose to adopt additional INSM practices such as those recommended by OpenPolicy. Moreover, OpenPolicy or other entities may advocate for OpenPolicy's recommendations in the NERC Reliability Standard development process.

B. Extending INSM to EACMS and PACS Beyond the Electronic Security Perimeter

1. NOPR

29. In the NOPR, the Commission described as overly narrow NERC's proposed application of the term CIP-networked environment because it was limited to assets and systems within the electronic security perimeter. The Commission explained that "Order No.

⁴⁷ NERC Comments at 2; OpenPolicy Comments at 3; Trade Associations Comments at 2.

⁴⁸ NERC Comments at 2; OpenPolicy Comments at 4. See *supra* note 22, explaining east-west communication.

887 used the term 'CIP-networked environment' purposefully to apply more broadly than the electronic security perimeter, specifically to include all assets and systems to which the CIP standards apply and may be the target of attacks."⁴⁹

30. In the NOPR, the Commission explained that excluding EACMS and PACS from the term CIP-networked environment is inconsistent with generally accepted approaches to cybersecurity. Under Reliability Standard CIP-002-5.1a and fundamental cybersecurity practices, similar systems within a network are grouped together to facilitate management, control, and monitoring of the networked environment.⁵⁰ The Commission explained that excluding certain grouped systems from protections—as is the case for EACMS and PACS in proposed Reliability Standard CIP-015-1—leaves other grouped systems within the CIP-networked environment at risk.⁵¹ A compromised EACMS grouping could provide an attacker with the ability to infiltrate other connected groups, such as BES Cyber Systems located within the electronic security perimeter, as an authenticated user or trusted communication.⁵²

31. The NOPR stated that attacks that threaten reliability can emanate from outside the electronic security perimeter from connected Cyber Assets, such as EACMS.⁵³ Declining to extend INSM implementation to EACMS and PACS outside the electronic security perimeter leaves a reliability gap because responsible entities will lack visibility into the high percentage of east-west traffic that occurs within the CIP-networked environment.⁵⁴

⁴⁹ NOPR, 188 FERC ¶ 61,175 at P 15.

⁵⁰ *Id.* P 16 (citing Reliability Standard CIP-002.5.1a (BES Cyber System Categorization) (categorizing EACMS, PACS, protected cyber assets, and BES Cyber Systems into groups); see, e.g., Nat'l Sec. Agency, *Network Infrastructure Security Guide* 1, 3-4 (Oct. 2023), https://media.defense.gov/2022/Jun/15/2003018261/-1/-1/0/CTR_NSA_NETWORK_INFRASTRUCTURE_SECURITY_GUIDE_20220615.PDF (recommending the grouping of similar network systems as a best practice for overall network security) (NSA Network Security Guide)).

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.* P 18 (citing CISA, *Cybersecurity Advisory: CISA Red Team Shares Key Findings to Improve Monitoring and Hardening of Networks*, 1, 2 (Feb. 2023), https://www.cisa.gov/sites/default/files/2023-03/aa23-059a-cisa_red_team_shares_key_findings_to_improve_monitoring_and_hardening_of_networks.pdf (CISA Cybersecurity Advisory)).

⁵⁴ *Id.* P 19. The National Institute of Standards and Technology (NIST) states that over 75% of network traffic is now east-west or server-to-server, i.e., traffic that is not covered by a perimeter-based defense approach. See NIST, *NIST SP 800-215*

2. Comments

a. Requests To Clarify the Scope of the Term CIP-Networked Environment

32. IRC, NERC, and Trade Associations request that the Commission provide greater clarity about the scope and reach of the term CIP-networked environment.⁵⁵ NERC and Trade Associations assert that the term is ambiguous and not defined.⁵⁶

33. NERC asks two clarifying questions. First, NERC asks whether, in extending the INSM protections to EACMS and PACS, would the term CIP-networked environment be restricted to east-west communications between EACMS and PACS outside of the electronic security perimeter.⁵⁷ Second, NERC asks whether the term should include the communications between PACS and controllers and communications to and from EACMS used solely for electronic access monitoring.⁵⁸

34. IRC recommends that the Commission clarify the term by specifying in a final rule “the networks located outside of a responsible entity’s Electronic Security Perimeter” that would be subject to INSM requirements.⁵⁹

35. OpenPolicy supports a broad definition of the term CIP-networked environment. It believes that the term must include information technology, operational technology, and Internet of Things systems and all converged assets to achieve the full potential of extending INSM implementation beyond the electronic security perimeter.⁶⁰ OpenPolicy claims this expansive definition of the term will mitigate risks associated with lateral movement and blind spots, providing comprehensive network security.⁶¹ Additionally, OpenPolicy asserts that incorporating operational technology systems into INSM frameworks is needed for segmenting and monitoring operational technology traffic to prevent lateral movement in industrial automation and control environments that can cause significant operation disruptions.⁶²

b. Directive To Extend INSM Implementation to EACMS and PACS Beyond the Electronic Security Perimeter

36. NERC, NESCOE, and OpenPolicy support the proposed directive to extend INSM implementation to EACMS and PACS outside of the electronic security perimeter.⁶³ NERC comments that it agrees with the Commission “that additional reliability benefits may be achieved by extending INSM implementation to EACMS and PACS beyond the electronic security perimeter.”⁶⁴

37. Likewise, NESCOE supports the proposed directive to extend the scope of INSM implementation, because the directive is aimed at closing a reliability and security gap that malicious actors could exploit to target the electric grid.⁶⁵ NESCOE explains that attackers could use network and supply chain attacks to bypass network perimeter-based security controls.⁶⁶

38. OpenPolicy states that the proposed “directive to extend INSM requirements beyond traditional electronic security perimeters is a commendable step forward.”⁶⁷ OpenPolicy explains that monitoring east-west traffic within trust zones enables the early detection of unauthorized activity that bypass traditional perimeter defenses, enhancing both incident response and risk management by providing a holistic view of potential vulnerabilities.⁶⁸ Further, OpenPolicy notes that EACMS and PACS are critical for operational control and that extending INSM implementation to EACMS and PACS addresses attacks that originate from connected cyber assets outside traditional trust zones.⁶⁹

39. Trade Associations oppose the Commission’s proposal to direct NERC to modify proposed Reliability Standard CIP–015–1 to expand the scope of INSM to include EACMS and PACS outside of the electronic security perimeter.⁷⁰ Trade Associations assert that INSM implementation should focus on the “most critical environment” (*i.e.*, networks protected by the electronic security perimeter) and should not be extended to EACMS and PACS.⁷¹ According to Trade Associations, the

industry would face budget, supply chain, and workforce constraints in extending INSM implementation to EACMS and PACS outside the electronic security perimeter.⁷² Trade Associations continue that industry may need to employ multiple tools to implement INSM inside and outside the electronic security perimeter due to differences in the operating environments, resulting in an increased volume of network traffic and false positives for events and causing alert fatigue.⁷³

40. Trade Associations further argue that, should the Commission require application of INSM to external EACMS and PACS, the Commission should allow the NERC standard drafting team flexibility to “focus on EACMS and PACS that have the greatest impact on grid security.”⁷⁴ Trade Associations assert that “not all EACMS and PACS are high risk” and continue that revisions to CIP Reliability Standards should be “risk based and outcome oriented.”⁷⁵ According to Trade Associations, EACMS and PACS that perform (or rely on) access control functions pose a higher risk, while those that perform a monitoring function such as a security information and event management solution presents a lower reliability risk. Consequently, Trade Associations aver that any revisions to the scope of proposed Reliability Standard CIP–015–1 account for “variations in the criticality and risk of these assets in order for it to be a risk-based Standard focused on protecting the most critical, high-risk assets that, for reliability, pose the greatest risk to the BES.”⁷⁶

41. Trade Associations also suggest that instead of directing NERC to extend INSM implementation at this time, the Commission should direct NERC to conduct a feasibility study after the Standard’s implementation to review intelligence reports about malicious activity targeting EACMS and PACS that may have a material impact on the reliability of the Bulk-Power System.⁷⁷ The feasibility study would help the Commission determine if there is residual risk to be addressed in other environments.⁷⁸ Finally, Trade Associations request that, if the Commission directs NERC to extend INSM implementation to EACMS and PACS outside the electronic security

Guide to a Secure Enterprise Network Landscape, 5 (Nov. 2022), <https://doi.org/10.6028/NIST.SP.800-215> (NIST SP 800–215).

⁵⁵ IRC Comments at 2; NERC Comments at 3; Trade Associations Comments at 8.

⁵⁶ NERC Comments at 3–4; Trade Associations Comments at 8, 12.

⁵⁷ NERC Comments at 5–6.

⁵⁸ *Id.* at 6.

⁵⁹ IRC Comments at 2.

⁶⁰ OpenPolicy Comments at 2.

⁶¹ *Id.*

⁶² *Id.* at 3.

⁶³ NERC Comments at 3; NESCOE Comments at 3; OpenPolicy Comments at 2.

⁶⁴ NERC Comments at 3.

⁶⁵ NESCOE Comments at 3.

⁶⁶ *Id.* at 3 n.10 (citing Order No. 887, 182 FERC ¶ 61,021 at P 15).

⁶⁷ OpenPolicy Comments at 2.

⁶⁸ *Id.*

⁶⁹ *Id.* at 2–3.

⁷⁰ Trade Associations Comments at 2, 6.

⁷¹ *Id.* at 6.

⁷² *Id.* at 6–7.

⁷³ *Id.* at 7.

⁷⁴ *Id.* at 8.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.* at 6, 8.

⁷⁸ *Id.* at 8.

perimeter, the Commission support NERC in establishing a noncompliance abeyance period in light of complexities and resource constraints associated with implementation of INSM.⁷⁹

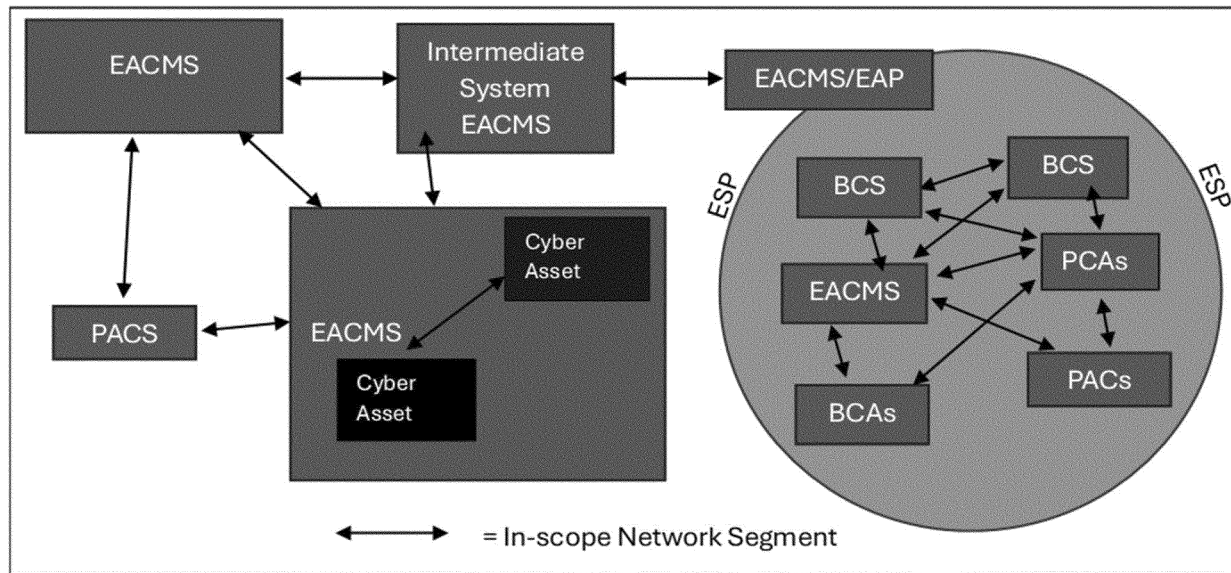
42. IC requests that the Commission should direct NERC to extend INSM implementation “to networks on which [EACMS] and [PACS] reside outside of a responsible entity’s Electronic Security Perimeter.”⁸⁰ IRC asks the Commission to clarify that the proposed directive to require INSM for EACMS and PACS external to the electronic security perimeter does not require “changes to the CIP-015-1 approach of directing responsible entities to use a risk-based rationale to implement network activity monitoring inside or outside an Electronic Security Perimeter.”⁸¹

3. Commission Determination

a. Scope of the Term CIP-Networked Environment

43. We are persuaded by the comments of NERC, IRC, and Trade Associations to clarify the scope of the term CIP-networked environment. First, the term CIP-networked environment does not cover all of a responsible entity’s network. Rather, the scope of CIP-networked environment includes the systems within the electronic security perimeter *and* one or more of the following: (1) network segments that are connected to EACMS and PACS outside of the electronic security perimeter; (2) network segments between EACMS and PACS outside of the electronic security perimeter; or (3) network segments that are internal to EACMS and PACS outside of the electronic security perimeter.⁸² We

determine that the above scope is appropriate because compromised EACMS and PACS outside the electronic security perimeter can provide an avenue for an attacker to access the operational technology environment inside the electronic security perimeter⁸³ to undertake any number of malicious acts as described in Order No. 887.⁸⁴ Implementation of INSM at each of the above networked segments should allow a responsible entity to detect and respond to malicious or unauthorized access to the electronic security perimeter. The below graphic depicts the CIP-networked environment (*i.e.*, the “trust zone”) that consists of the Cyber Systems, including the delineated networked segments mentioned in this paragraph (documented in arrows), that are subject to the INSM requirements of this final rule.



44. The term CIP-networked environment is inclusive of EACMS and PACS necessary to protect all trust zones of the term⁸⁵ and extends beyond the electronic security perimeter to guard against attackers moving east-west within the EACMS or PACS network segments of the term.⁸⁶

45. Consistent with the additional clarity about the scope of the term CIP-networked environment provided above, we answer NERC’s questions. First, in extending proposed Reliability Standard CIP-015-1 to EACMS and PACS, CIP-networked environment encompasses east-west traffic within EACMS networks and PACS networks,

as well as east-west traffic between EACMS and PACS, in addition to east-west traffic within the electronic security perimeter. Second, communication between PACS and controllers and communications to and from EACMS used solely for electronic access monitoring are included in the term CIP-networked environment.

⁷⁹ *Id.* at 12.

⁸⁰ IRC Comments at 2.

⁸¹ *Id.*

⁸² To clarify, the CIP-networked environment is comprised of all high impact BES Cyber Systems and medium impact BES Cyber Systems with external routable connectivity that are subject to CIP Reliability Standards and may be targets of attacks. See NOPR, 188 FERC ¶ 61,175 at P 15.

⁸³ See CISA, *Cybersecurity Advisory: CISA Red Team Shares Key Findings to Improve Monitoring*

and Hardening of Networks, 2, 14 (Feb. 2023), https://www.cisa.gov/sites/default/files/2023-03/aa23-059a-cisa_red_team_shares_key_findings_to_improve_monitoring_and_hardening_of_networks.pdf (finding that insufficient network monitoring contributed to a CISA red team avoiding detection and gaining access to an organization’s network through a compromised domain controller, typically located at an EACMS).

⁸⁴ Order No. 887, 182 FERC ¶ 61,021 at P 19 (“Further, without INSM, an attacker could exploit

legitimate cyber resources to: (1) escalate privileges (*i.e.*, exploit a software vulnerability to gain administrator account privileges); (2) move undetected inside the trust zone of the CIP-networked environment; or (3) execute unauthorized code (*e.g.*, a virus or ransomware).”).

⁸⁵ *Id.* P 14.

⁸⁶ See NIST SP 800-215 at 5; NSA Network Security Guide at 3.

46. We note that one aspect of OpenPolicy's recommended definition of the term CIP-networked environment is already incorporated into the delineated network segments discussed above: implementation of INSM at operational technology environments,⁸⁷ guarding against disruptions in industrial and control environments.⁸⁸ OpenPolicy's proposal to extend the definition of the term CIP-networked environment to include information technology and Internet of Things environments⁸⁹ is outside the scope of this proceeding, which focuses on INSM implementation in operational technology environments.

b. Directive To Extend INSM to EACMS and PACS Outside the Electronic Security Perimeter

47. Pursuant to section 215(d)(5) of the FPA, we adopt the NOPR proposal to direct NERC to develop modifications to proposed Reliability Standard CIP–015–1 to extend INSM implementation to EACMS and PACS outside of the electronic security perimeter. We find that proposed Reliability Standard CIP–015–1 is not fully responsive to the directive in Order No. 887 to implement INSM within the CIP-networked environment because proposed Reliability Standard CIP–015–1 excludes EACMS and PACS, which leaves a security gap.

48. We agree with commenters that extending INSM implementation to EACMS and PACS outside the electronic security perimeter provides reliability benefits by closing a reliability and security gap through addressing potential attack vectors that originate outside the trust zone.⁹⁰ Extending INSM implementation ensures that BES Cyber Systems benefit from monitoring of east-west traffic

within groups of EACMS and PACS.⁹¹ The inclusion of EACMS and PACS enhances early detection of anomalous or malicious activity. Accordingly, our directive fills a reliability gap by addressing potential avenues for attackers to infiltrate BES Cyber Systems within the electronic security perimeter.⁹²

49. We are unpersuaded by Trade Associations' arguments for opposing the extension of INSM implementation to EACMS and PACS outside of the electronic security perimeter. The "most critical environment" is broader than envisioned by Trade Associations. As a NIST guidance document explains, INSM improves the probability of detection for anomalous or malicious activity and should not be isolated to the most critical trust zone (*i.e.*, the electronic security perimeter).⁹³ Otherwise, a threat already in the most critical trust zone can move laterally within the network and remain undetected for an extended period of time.⁹⁴ A threat that can move laterally within the network can threaten the reliability of the Bulk-Power System.⁹⁵

50. In fine, "access controls" in the EACMS acronym refer to user passwords and other information that, once compromised, enables an adversary to enter and move undetected within a network.⁹⁶ These are known

targets for malicious actors.⁹⁷ The risk is similar regardless of whether EACMS and PACS reside inside or external to the electronic security perimeter.

51. Likewise, we disagree with Trade Associations' assertion that meaningful distinctions can be made within categories of EACMS and PACS based on level of risk. Trade Associations acknowledge what they characterize as the higher risk associated with EACMS and PACS that perform access control functions but suggest that those performing monitoring functions pose a lesser risk. This distinction is unfounded.⁹⁸ EACMS and PACS that perform monitoring functions also are susceptible to a level of risk that warrant INSM. For example, a compromised monitoring system such as the security information and event management referenced by Trade Associations at minimum gives a malicious actor visibility to information used to control network access. Such reconnaissance can be used by an actor to pre-position for a cyber attack.⁹⁹ In other words, an adversary that has gained access to a monitoring system can then obtain the information needed to establish a trusted connection and compromise the electronic security perimeter. Thus, while one or more additional steps may be involved, the risk of network compromise remains high once an adversary gains access to a monitoring system. Regardless of the function of the EACMS, it can serve as a gateway for a malicious actor to compromise the electronic security perimeter and

⁹¹ See CISA Cybersecurity Advisory at 2, 14 (finding that insufficient network monitoring contributed to a CISA red team avoiding detection and gaining access to an organization's network through lateral movement by leveraging access to an identity and access management system, *e.g.*, Active Directory serving as an electronic access control system); NIST SP 800–215 at 5 (describing the limitations of a perimeter-based security approach as not capturing threats from inside a network that can move laterally and remain undetected for an extended period of time); NIST SP 800–82r3 at 74 (recommending the analyzing of information to differentiate between known and unknown communication as a necessary first step in implementing network security monitoring). The term INSM is used by the Commission in Order No. 887, but the cybersecurity industry uses the term "network security monitoring."

⁹² See CISA Cybersecurity Advisory at 2–6 (describing how a CISA Red Team gained access to workstations and servers from an identity and access management system serving as an electronic access control system, which assisted in lateral movement to other networks).

⁹³ See NIST SP 800–215 at 5 (describing east-west traffic as "largely invisible to security teams" without INSM and that a threat inside a network can move east-west and "remain undetected for days or even months").

⁹⁴ *Id.*

⁹⁵ See CISA Cybersecurity Advisory at 2, 14 (a CISA red team avoided detection and gained access to an organization's network through lateral movement by leveraging access to an identity and access management system serving as an electronic access control system).

⁹⁶ For example, virtual private network (VPN) connections fit the definition of EACMS.

⁹⁷ See Aus Gov't Et Al., Detecting and Mitigating Active Directory Compromises ii (Jan. 2025), <https://www.cyber.gov.au/sites/default/files/2024-09/PROTECT-Detecting-and-Mitigating-Active-Directory-Compromises.pdf> (explaining that one such EACMS "is susceptible to compromise due to its permissive default settings, its complex relationships, and permissions. . . . These issues are commonly exploited by malicious actors to compromise" the system).

⁹⁸ Further, we note that the NERC Glossary definition of EACMS explicitly includes both electronic access controls and electronic access monitoring. See NERC Glossary (defining EACMS as "Cyber Assets that perform electronic access control or electronic access *monitoring* of the Electronic Security Perimeter(s) or BES Cyber Systems . . ." (emphasis added)). We are concerned that Trade Associations' suggestion to distinguish among categories of EACMS would effectively modify the NERC Glossary definition of EACMS.

⁹⁹ See CISA, Joint Cybersecurity Advisory: PRC State-Sponsored Actors Compromise and Maintain Persistent Access to U.S. Critical Infrastructure 6, 9 (Feb. 2024), https://www.cisa.gov/sites/default/files/2024-03/aa24-038a_csa_prc_state_sponsored_actors_compromise_us_critical_infrastructure_3.pdf (describing how Volt Typhoon actors conducted extensive pre-compromise reconnaissance to learn about the target organization, its network, and its staff in advance of a possible cyber attack) (PRC State-Sponsored Actors Joint Cybersecurity Advisory).

⁸⁷ OpenPolicy Comments at 2. The NIST Glossary defines operational technology to mean "[p]rogrammable systems or devices that interact with the physical environment (or manage devices that interact with the physical environment). These systems/devices detect or cause a direct change through the monitoring and/or control of devices, processes, and events. Examples include industrial control systems, building management systems, fire control systems, and physical access control mechanisms." NIST, *Computer Security Resource Center, Glossary* (Mar. 10, 2022), <https://csrc.nist.gov/glossary>.

⁸⁸ See NIST, *NIST SP 800–82r3 Guide to Operational Technology (OT) Security*, 1, 12 (Sept. 2023), <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-82r3.pdf> (describing operational technology security as vital to the operation of critical U.S. infrastructure, including electrical utility transmission and distribution systems) (NIST SP 800–82r3).

⁸⁹ OpenPolicy Comments at 2.

⁹⁰ NERC Comments at 3; NESCOE Comments at 3; OpenPolicy Comments at 2.

therefore the EACMS warrants protection through INSM implementation.

52. We recognize that NERC in modifying the Standard in response to the directive in this final rule retains the ability to propose an equally efficient and effective solution to determining which EACMS and PACS outside of the electronic security perimeter should be covered by the Standard. However, we caution that Trade Associations' approach appears to fall short of that criteria as it would leave a reliability gap that malicious actors could exploit by using EACMS and PACS outside the electronic security perimeter to penetrate the electronic security perimeter. The additional clarity provided in this final rule should be sufficient for the drafting team to develop a Reliability Standard that is fully responsive to the directive in Order No. 887 to implement INSM within the CIP-networked environment.

53. We are unpersuaded by the Trade Associations' contention that if INSM implementation is not limited to EACMS and PACS that "most disproportionately affect the grid," it could lead to "costly and inefficient deployments and increased traffic" as EACMS and PACS do not share the same requirements as operating technology protocols.¹⁰⁰ Trade Associations provide no evidence for this claim. We believe that the benefits of implementing INSM at the network segments listed above will outweigh the costs of doing so because they are high value targets that if compromised would allow an attacker to infiltrate the perimeter as a trusted communication.¹⁰¹ Further, responsible entities can take certain steps to mitigate the cost impacts of extending INSM to EACMS and PACS outside the electronic security perimeter by implementing INSM in a risk-based manner pursuant to Requirement R1.1 of proposed Reliability Standard CIP-015-1. For example, a responsible entity could define incident alert thresholds and establish a baseline for normal network activity that could reduce the cost of retaining and protecting INSM data under Requirements R2 and R3, respectively, by reducing the amount of

INSM data responsible entities must collect.¹⁰²

54. Similarly, in response to the Trade Associations' claim that INSM implementation outside of the electronic security perimeter may require the use of multiple tools that could result in increased traffic and false positives that cause alert fatigue,¹⁰³ we remind responsible entities that they will determine how to implement INSM based on their architecture and tools (subject to oversight by the compliance enforcement authority), even if revised Reliability Standard CIP-015-1 mandates which cyber assets are subject to INSM requirements. Again, that could mean setting incident alert thresholds and creating baselines for network activity that alert responsible entities only of network traffic that has indicia of malicious intent, reducing the potential for false positive and alert fatigue.

55. Regarding whether to support NERC's potential future establishment of a noncompliance abeyance,¹⁰⁴ we decline to prejudge the need for such a period. We also decline to direct NERC to conduct a feasibility study that includes a review of threat intelligence information containing indicia of malicious activity targeting EACMS or PACS that may have a material impact on the reliability of the Bulk-Power System.¹⁰⁵ This threat is already well-established, and a feasibility study is unnecessary. For example, open-source intelligence reports indicate that malicious actors are targeting an identity and access management system, serving as an electronic access control system, to enable lateral movement—the type of movement INSM is intended to detect and respond to—to gain access to critical operational technology trust zones that can disrupt electrical substations, impacting Bulk-Power System reliability.¹⁰⁶ Similarly, a 2024

CISA cybersecurity alert warned that threat actors were actively exploiting vulnerabilities in certain VPNs that are a type of EACMS used in the electric industry.¹⁰⁷ In addition, NERC's 2024 Annual Report on Cyber Security Incidents noted that two of the three cybersecurity incidents in the report involving the Bulk-Power System were attempts to compromise EACMS outside of the electronic security perimeter.¹⁰⁸ These reports demonstrate that the threat to EACMS and PACS outside of the electronic security perimeter is well-documented and illustrate the residual risk to be addressed in environments outside of the electronic security perimeter.

56. We decline IRC's request to specify the networks located outside of the electronic security perimeter that would be covered by the directed modifications to proposed Reliability Standard CIP-015-1. Such a step is unnecessary following our clarification above regarding the term CIP-networked environment.

C. The Implementation Timeline To Develop Modifications to CIP-015-1

1. NOPR

57. In the NOPR, the Commission proposed to direct NERC to submit the revised Reliability Standard CIP-015-1 extending INSM implementation to EACMS and PACS outside the electronic security perimeter for Commission approval within 12 months of the effective date of a final rule in this proceeding.¹⁰⁹

2. Comments

58. NERC asks the Commission to provide at least 12 months to modify Reliability Standard CIP-015-1, explaining that it is addressing multiple high priority projects as part of its large workload on Commission directives.¹¹⁰

disruptions, such as disrupting electrical substations).

¹⁰⁷ CISA, *Cisco Releases Security Updates Addressing ArcaneDoor, Vulnerabilities in Cisco Firewall Platforms* (Apr. 2024), <https://www.cisa.gov/news-events/alerts/2024/04/24/cisco-releases-security-updates-addressing-arcanedoor-vulnerabilities-cisco-firewall-platforms>; NERC Glossary. VPNs are commonly used in the electrical industry and if successfully targeted can cause significant operational disruptions in the industry. Dragos, *Why Adversaries Target VPN Appliances: The Pathway from IT to OT Cyber Attack*, (Sept. 30, 2024) <https://www.dragos.com/blog/why-adversaries-target-vpn-appliances-the-pathway-from-it-to-ot-cyber-attack/>.

¹⁰⁸ N. Am. Elec. Reliability Corp., Annual Report of the North American Electric Reliability Corporation on Cyber Security Incidents, Docket No. RM18-2-000 (filed Mar. 21, 2025).

¹⁰⁹ NOPR, 188 FERC ¶ 61,175 at P 21.

¹¹⁰ NERC Comments at 6-7 (as of November 2024, NERC is working on responding to 82 outstanding

¹⁰² As requested by IRC, we affirm that the directive in this final rule requires no changes to proposed Reliability Standard CIP-015-1 Requirement R1.1 regarding use of a risk-based approach to implement network activity monitoring.

¹⁰³ Trade Associations Comments at 7.

¹⁰⁴ N. Am. Elec. Reliability Corp., 189 FERC ¶ 61,211 (2024) (approving NERC's 2024 five-year performance assessment); N. Am. Elec. Reliability Corp., Supplemental Filing, Docket No. RR24-4-000, at 12 (filed Nov. 8, 2024) ("During the standards development process of new and modified Reliability Standards, the ERO Enterprise will consider whether draft Reliability Standards are good candidates for a Potential Noncompliance abeyance period.").

¹⁰⁵ Trade Associations Comments at 8.

¹⁰⁶ See PRC State-Sponsored Actors Joint Cybersecurity Advisory at 6-7, 14 (describing how Volt Typhoon attacks achieved full domain compromise by extracting an identity and access management system database that enables potential

¹⁰⁰ Trade Associations Comments at 9.

¹⁰¹ See, e.g., CISA Cybersecurity Advisory at 14 (finding a CISA red team gained access to an organization's network due to the lack of monitoring on endpoint management systems—high valued assets—that can include the monitoring system part of an EACMS); NIST SP 800-215 at 5; NSA Network Security Guide at 2.

NERC notes that providing more than 12 months for implementation of the final rule would allow for additional development options, including a technical conference near the beginning of the development process to promote efficient development and drafting.¹¹¹ Additionally, more than 12 months would allow NERC to balance resources between competing high priority projects.

59. Trade Associations express concern that a drafting team may not be able to deliver a Standard within 12 months and ask that the Commission grant NERC the discretion to determine when to submit to the Commission the modification to Reliability Standard CIP-015-1.¹¹² Further, Trade Associations explain that implementation of the final rule should be extended because the scope of the directed modification may be impacted by Project 2023-09 Risk Management for Third-Party Cloud Services' possible revision of the definition of EACMS.¹¹³ Trade Associations claim that revisions to the definition of EACMS would have significant implications for the scope of modifications to Reliability Standard CIP-015-1. Trade Associations also argue that a timeline extension is necessary as the expansion in the scope of the Standard may not be as simple as "adding additional applicability to the drafted requirements" of Reliability Standard CIP-015-1.¹¹⁴ Finally, Trade Associations request that the Commission consider organizing a technical workshop or conference as part of the project timeline to define the scope and technical justification of the directed modification to Reliability Standard CIP-015-1.¹¹⁵

3. Commission Determination

60. Based on our consideration of the record, we adopt the 12-month deadline proposed in the NOPR. While we recognize that parties might benefit from additional time, we are not persuaded at this time that additional time is needed to address the modifications directed in this order. To the extent NERC concludes during the standards drafting process that additional time is needed, NERC may request, and the Commission will consider whether to grant, an extension at that time.

III. Information Collection Statement

61. The FERC-725B information collection requirements are subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act of 1995. OMB's regulations require approval of certain information collection requirements imposed by agency rules. Upon approval of a collection of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number. The Commission received no comments on the validity of the burden and cost estimates in the NOPR.

62. The Commission solicits comments on the need for this information, whether the information will have practical utility, the accuracy of the burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden,

including the use of automated information techniques.

63. The Commission bases its paperwork burden estimates on the additional paperwork burden presented by the proposed revision to Reliability Standard CIP-015-1, as this is a new proposed Reliability Standard. Reliability Standards are objective-based and allow entities to choose compliance approaches best tailored to their systems. Reliability Standard CIP-015-1 does not require applicable entities to submit any filings with either the Commission or NERC as the ERO. Entities, however, are required to maintain documentation adequate to demonstrate compliance with the Reliability Standard. Commission and NERC staff conduct periodic audits of entities and auditors rely on the entity's documentation in determining compliance with a Reliability Standard. While entities retain flexibility on how they choose to demonstrate compliance, the Reliability Standard includes Compliance Measures providing examples of the type of documentation an entity may want to develop and maintain to demonstrate compliance. The reporting burden below is based on the Compliance Measurements provided in Reliability Standard CIP-015-1.

64. The NERC Compliance Registry, as of April 2025, identifies approximately 1,636 unique U.S. entities that are subject to mandatory compliance with CIP Reliability Standards. Of this total, we estimate that 400 entities will face an increased paperwork burden under proposed Reliability Standard CIP-015-1. Based on these assumptions, we estimate the following reporting burden:

ANNUAL CHANGES IN THE FINAL RULE IN DOCKET NO. RM24-7-000¹¹⁶

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ¹¹⁷	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Create one or more documented process(es) (R1).	400	1	400	40 hrs.; \$3,410	16,000 hrs.; \$1,364,160 ..	\$3,410
Create documentation detailing network data feed(s) and reason (R1.1).	400	1	400	60 hrs.; \$5,116	24,000 hrs.; \$2,046,240 ..	5,116
Create documentation of: anomalous events and baseline used to detect anomalous events (R1.2).	400	1	400	60 hrs.; \$5,116	24,000 hrs.; \$2,046,240 ..	5,116
Create documentation of methods to: evaluate anomalous activity; response to detected activity; and escalation process(es) (R1.3).	400	1	400	60 hrs.; \$5,116	24,000 hrs.; \$2,046,240 ..	5,116
Create documentation of: data retention process(es); system configuration(s), or system-generated report(s) (R2).	400	1	400	60 hrs.; \$5,116	24,000 hrs.; \$2,046,240 ..	5,116

Commission directives through the Standards Development process).

¹¹¹ *Id.* at 7-8.

¹¹² Trade Associations Comments at 10-11.

¹¹³ *Id.* at 12.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

ANNUAL CHANGES IN THE FINAL RULE IN DOCKET NO. RM24-7-000¹¹⁶—Continued

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ¹¹⁷	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Create documentation of how the collected data is being protected (R3).	400	1	400	60 hrs.; \$5,116	24,000 hrs.; \$2,046,240 ..	5,116
Total burden for FERC-725B(5) under CIP-015-1.			2,400		136,000 hrs.; \$11,595,360.	32,116

65. The estimated responses and burden hours for Years 1–3 will total respectively as follows:

- Year 1–3 each: 2,400 responses; 136,000 hours.

66. The annual cost burden for each year One to Three is \$11,595,360.

67. *Title:* Mandatory Reliability Standards, Revised Critical Infrastructure Protection Reliability Standards.

Action: Revision to FERC-725B information collection.

OMB Control No.: 1902-0248.

Respondents: Businesses or other for-profit institutions; not-for-profit institutions.

Frequency of Responses: On Occasion.

Necessity of the Information: This final rule approves the requested modifications to Reliability Standards pertaining to critical infrastructure protection. As discussed above, the Commission approves proposed Reliability Standard CIP-015-1 pursuant to section 215(d)(2) of the FPA because it improves upon the currently effective suite of cybersecurity CIP Reliability Standards.

Internal Review: The Commission has reviewed the proposed Reliability Standard and made a determination that its action is necessary to implement section 215 of the FPA.

68. Interested persons may obtain information on the reporting

requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426 [Attention: Kayla Williams, Office of the Executive Director, email: DataClearance@ferc.gov, phone: (202) 502-8663, fax: (202) 273-0873].

IV. Environmental Analysis

69. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.¹¹⁸ The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.¹¹⁹ The action proposed herein falls within this categorical exclusion in the Commission's regulations.

V. Regulatory Flexibility Act

70. The Regulatory Flexibility Act of 1980 (RFA)¹²⁰ generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.¹²¹ The SBA revised its size standard for electric utilities (effective March 17, 2023) to a standard based on the number of employees, including affiliates (from the prior standard based on megawatt hour sales).¹²² The Commission believes that because the obligations imposed upon industry are directed only at entities that own or operate high impact BES

Cyber Systems with or without external routable connectivity or medium impact BES Cyber Systems with external routable connectivity, only a minimal number of entities will meet the SBA revised standard for electric utilities. Only a minimal number of entities will satisfy the SBA revised standard because small entities do not typically own or operate any kind of high impact BES Cyber Systems or medium impact BES Cyber systems with external routable connectivity. Therefore, the Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Accordingly, no regulatory flexibility analysis is required.

VI. Document Availability

71. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>).

72. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

73. User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at 202-502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.reference@ferc.gov.

VII. Effective Date and Congressional Notification

74. These regulations are effective September 2, 2025.

The Commission has determined, with the concurrence of the

¹¹⁶ The paperwork burden estimate includes costs associated with the initial development of a policy to address the requirements.

¹¹⁷ This burden applies in Year One to Year Three.

The loaded hourly wage figure (includes benefits) is based on the average of three occupational categories for May 2024 Wages found on the Bureau of Labor Statistics website (http://www.bls.gov/oes/current/naics2_22.htm). The loaded hourly wage includes fringe benefits divided by 81.70%. See <https://data.bls.gov/oes/#/industry/000000>.

Legal Occupations (90th percentile) (Occupation Code: 23-0000): \$140.76.

Electrical Engineer (mean) (Occupation Code: 17-2071): \$71.19.

Office and Administrative Support (90th percentile) (Occupation Code: 43-0000): \$43.83.

(\$140.76 + \$71.19 + \$43.83) ÷ 3 = \$85.26.

The figure is rounded to \$85.00 for use in calculating wage figures in this final rule.

¹¹⁸ *Reguls. Implementing the Nat'l Env't Pol'y Act*, Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. Preambles 1986-1990 ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

¹¹⁹ 18 CFR 380.4(a)(2)(ii).

¹²⁰ 5 U.S.C. 601-612.

¹²¹ 13 CFR 121.101.

¹²² 13 CFR 121.201, Subsector 221 (Utilities).

Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a “major rule” as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

Issued: June 26, 2025.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2025–12309 Filed 7–1–25; 8:45 am]

BILLING CODE 6717–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation’s regulation on Allocation of Assets in Single-Employer Plans to prescribe the spreads component of the interest assumption under the asset allocation regulation for plans with valuation dates of July 31, 2025–October 30, 2025. These interest assumptions are used for valuing benefits under terminating single-employer plans and for other purposes.

DATES: Effective July 31, 2025.

FOR FURTHER INFORMATION CONTACT: Monica O’Donnell (*odonnell.monica@pbgc.gov*), Attorney, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101, 202–229–5507. If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: PBGC’s regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes actuarial assumptions—including an interest assumption—for valuing benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974 (ERISA). The interest assumption is also posted on PBGC’s website (*www.pbgc.gov*).

PBGC uses the interest assumption in § 4044.54 to determine the present value of annuities in an involuntary or distress termination of a single-employer plan under the asset allocation regulation. The assumptions in part 4044 of PBGC’s regulations are

also used in other situations where it is appropriate for liabilities to align with private sector group annuity prices. For example, PBGC’s regulations on Notice, Collection, and Redetermination of Withdrawal Liability (29 CFR part 4219) and Duties of Plan Sponsor Following Mass Withdrawal (29 CFR part 4281) provide that these assumptions are used to value liabilities for purposes of determining withdrawn employers’ reallocation liability in the event of a mass withdrawal from a multiemployer plan. Multiemployer plans that receive special financial assistance under the regulation on Special Financial Assistance by PBGC (29 CFR part 4262) must, as a condition of receiving special financial assistance, use the interest assumption to determine withdrawal liability for a prescribed period. Additionally, plan sponsors are required to use some, or all of these assumptions for specified purposes (*e.g.*, reporting benefit liabilities in filings required under PBGC’s regulation on Annual Financial and Actuarial Information Reporting (29 CFR part 4010) or determining certain amounts to transfer to PBGC’s Missing Participants Program on behalf of a missing participant of a terminating defined benefit plan under PBGC’s regulation on Missing Participants (29 CFR part 4050)) and may use them for other purposes (*e.g.*, to ensure that plan spinoffs comply with section 414(l) of the Internal Revenue Code).

Part 4044 of PBGC’s regulations provides that the interest assumption for part 4044 purposes is a yield curve (*i.e.*, the “4044 yield curve”) that is based on a blend of two publicly available bond yield curves that is adjusted to the extent necessary so that the resulting liabilities align with group annuity prices. The adjustments are referred to as “spreads.” PBGC determines and publishes spreads quarterly based on survey data on pricing of private-sector group annuities. PBGC posts the 4044 yield curve on its website at *www.pbgc.gov* each month shortly after its underlying data become available. In addition, practitioners are able to determine the 4044 yield curve as of the end of any month using the publicly available bond yield curves and the spreads specified in the regulation.

This rule amends the regulation to specify the spreads used to determine the 4044 yield curve as of the last days of July, August, and September of 2025 (*i.e.*, the “third quarter 2025 spreads”). Due to space constraints, table 1 to paragraph (e) shows spreads for only the most recent four quarters. Because the third quarter 2025 spreads would be the fifth set of spreads, this rule removes the

third quarter 2024 spreads. In the future, PBGC similarly plans to remove the oldest of the spreads. Historical spreads are available on *www.pbgc.gov*, along with more recent spreads.

This rule also amends paragraphs (e)(3)(i) and (e)(3)(ii) of § 4044.54, which provide examples of how to choose the appropriate blended market yield curve and spreads for a given valuation date. These examples currently direct practitioners to use table 1 to paragraph (e) to find the applicable spreads for the valuation date. PBGC is amending the examples by directing practitioners to the quarterly spreads available on PBGC’s website, *www.pbgc.gov*, instead of to table 1 to paragraph (e) so that the wording of the examples does not need to be updated with the passage of time.

Need for Immediate Guidance

PBGC has determined that notice of, and public comment on, this rule are impracticable, unnecessary, and contrary to the public interest. PBGC routinely updates the spreads component of the interest assumption in the asset allocation regulation so that the 4044 yield curve may be determined as soon as the underlying bond yield curves become available. These amendments are merely technical; they ensure that use of PBGC’s interest assumption continues to yield liabilities in line with group annuity prices. Accordingly, PBGC finds that the public interest is best served by issuing this rule expeditiously, without an opportunity for notice and comment, and that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a “significant regulatory action” under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

For the reasons stated in the preamble, PBGC amends 29 CFR part 4044 as follows.

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 2. Amend § 4044.54 by revising paragraphs (e)(3)(i) and (ii) and table 1 to paragraph (e) to read as follows:

§ 4044.54 Interest assumptions.

* * * *

(e) * * *

(3) * * *

(i) *Example 1—August 31, 2024, valuation date.* Because the valuation date is the last day of a month, the

applicable blended market yield curve determined under paragraph (d)(1) of this section is the blended market yield curve as of that date. Because August 31, 2024, is in the third calendar quarter of 2024, the applicable spreads are the third quarter 2024 spreads, available on www.pbgc.gov.

(ii) *Example 2—November 15, 2024, valuation date.* Because the valuation date is not the last day of a month, the

applicable blended market yield curve determined under paragraph (d)(1) of this section is the blended market yield curve as of the last day of the month before the month containing the valuation date, October 31, 2024. Because October 31, 2024, is in the fourth calendar quarter of 2024, the applicable spreads are the fourth quarter 2024 spreads, available on www.pbgc.gov.

TABLE 1 TO PARAGRAPH (e)—SPREADS

Maturity point	Fourth quarter 2024 spreads (percent)	First quarter 2025 spreads (percent)	Second quarter 2025 spreads (percent)	Third quarter 2025 spreads (percent)
0.5	0.33	0.36	0.38	0.40
1.0	0.33	0.36	0.38	0.40
1.5	0.33	0.36	0.37	0.40
2.0	0.33	0.36	0.37	0.40
2.5	0.33	0.36	0.37	0.40
3.0	0.33	0.36	0.37	0.40
3.5	0.33	0.36	0.37	0.39
4.0	0.33	0.36	0.37	0.39
4.5	0.33	0.36	0.37	0.39
5.0	0.33	0.36	0.37	0.39
5.5	0.32	0.35	0.36	0.38
6.0	0.32	0.35	0.36	0.38
6.5	0.32	0.35	0.35	0.37
7.0	0.32	0.35	0.35	0.37
7.5	0.32	0.35	0.35	0.36
8.0	0.32	0.35	0.35	0.36
8.5	0.32	0.34	0.34	0.34
9.0	0.32	0.34	0.34	0.34
9.5	0.32	0.34	0.33	0.33
10.0	0.32	0.34	0.33	0.33
10.5	0.32	0.33	0.32	0.32
11.0	0.32	0.33	0.32	0.32
11.5	0.32	0.33	0.32	0.30
12.0	0.32	0.33	0.32	0.30
12.5	0.32	0.32	0.31	0.28
13.0	0.32	0.32	0.31	0.28
13.5	0.31	0.32	0.30	0.27
14.0	0.31	0.32	0.30	0.27
14.5	0.31	0.31	0.29	0.25
15.0	0.31	0.31	0.29	0.25
15.5	0.31	0.30	0.28	0.24
16.0	0.31	0.30	0.28	0.24
16.5	0.31	0.30	0.27	0.22
17.0	0.31	0.30	0.27	0.22
17.5	0.31	0.29	0.26	0.20
18.0	0.31	0.29	0.26	0.20
18.5	0.31	0.29	0.25	0.19
19.0	0.31	0.29	0.25	0.19
19.5	0.30	0.28	0.24	0.17
20.0	0.30	0.28	0.24	0.17
20.5	0.30	0.28	0.23	0.16
21.0	0.30	0.28	0.23	0.16
21.5	0.30	0.27	0.22	0.14
22.0	0.30	0.27	0.22	0.14
22.5	0.30	0.27	0.22	0.13
23.0	0.30	0.27	0.22	0.13
23.5	0.30	0.26	0.21	0.12
24.0	0.30	0.26	0.21	0.12
24.5	0.30	0.26	0.20	0.11
25.0	0.30	0.26	0.20	0.11
25.5	0.30	0.26	0.20	0.10
26.0	0.30	0.26	0.20	0.10
26.5	0.30	0.26	0.20	0.09
27.0	0.30	0.26	0.20	0.09
27.5	0.30	0.25	0.19	0.09
28.0	0.30	0.25	0.19	0.09
28.5	0.30	0.25	0.19	0.09

TABLE 1 TO PARAGRAPH (e)—SPREADS—Continued

Maturity point	Fourth quarter 2024 spreads (percent)	First quarter 2025 spreads (percent)	Second quarter 2025 spreads (percent)	Third quarter 2025 spreads (percent)
29.0	0.30	0.25	0.19	0.09
29.5	0.30	0.25	0.19	0.09
30.0	0.30	0.25	0.19	0.09

* * * * *

Dated: June 26, 2025.

Hilary Duke,Assistant General Counsel for Regulatory
Affairs, Pension Benefit Guaranty
Corporation.

[FR Doc. 2025–12319 Filed 7–1–25; 8:45 am]

BILLING CODE 7709–02–P

**DEPARTMENT OF HOMELAND
SECURITY****Coast Guard****33 CFR Part 100**

[Docket No. USCG–2025–0575]

**Special Local Regulations; Beaufort
Water Festival and Beaufort Water
Festival Air Show, Beaufort, SC****AGENCY:** Coast Guard, DHS.**ACTION:** Notification of enforcement of
regulation.

SUMMARY: The Coast Guard will enforce special local regulations for the Beaufort Water Festival and Beaufort Water Festival Air Show events from July 11 through 20, 2025, to provide for the safety of life on navigable waterways during these events. Our regulation for marine events within the Seventh Coast Guard District identifies the regulated areas for these annual events in Beaufort, SC. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 100.704 will be enforced for the special local regulations identified in the **SUPPLEMENTARY INFORMATION** section below for the dates and times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Marine Science Technician First Class Thomas J. Welker, Sector Charleston Waterways Management Division, U.S. Coast Guard; telephone 843–740–3180 ext. 3339, email at CharlestonWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local

regulations in 33 CFR 100.704 for the Beaufort Water Festival event listed in Item No. 7 in Table 1 to § 100.704, from 8 a.m. until 5 p.m. each day from July 11, 2025, through July 20, 2025, and for the Beaufort Water Festival Air Show event listed in Item No. 8 in Table 1 to § 100.704, from noon to 5 p.m. on July 19, 2025. This action is being taken to provide for the safety of life on navigable waterways during this swim event. Our regulation for Marine Events within the Captain of the Port Charleston, § 100.704, Table 1 to § 100.704, Items No. 7 and 8, specifies the location of the regulated areas for the Beaufort Water Festival and Beaufort Water Festival Air Show. Under the provisions of § 100.704(c), all persons and vessels are prohibited from entering the regulated area, except those persons and vessels participating in the event, unless they receive permission to do so from the Coast Guard Patrol Commander, or designated representative.

The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation. In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide notice of the regulated area via Local Notice to Mariners, Marine Safety Information Bulletins, Broadcast Notice to Mariners, and on-scene designated representatives.

F.J. DelRosso,Captain, U.S. Coast Guard, Captain of the
Port Charleston.

[FR Doc. 2025–12331 Filed 7–1–25; 8:45 am]

BILLING CODE 9110–04–P

**DEPARTMENT OF HOMELAND
SECURITY****Coast Guard****33 CFR Part 165**

[Docket Number USCG–2025–0462]

RIN 1625–AA00

**Safety Zone; Laguna Madre, South
Padre Island, TX****AGENCY:** Coast Guard, DHS.**ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters in the Laguna Madre. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a series of fireworks displays launched from a barge in the Laguna Madre, South Padre Island, Texas. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Corpus Christi or a designated representative.

DATES: This rule is effective without actual notice from July 2, 2025 through July 30, 2025. For the purposes of enforcement, actual notice will be used from June 26, 2025, until July 2, 2025. It will be subject to enforcement from the hours of 9 p.m. through 11:59 p.m. each of the following dates: June 27; July 1, 8, 11, 15, 18, 22, 25, and 29.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0462 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 Timothy Cardenas, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–244–4784, email Timothy.J.Cardenas@uscg.mil.

SUPPLEMENTARY INFORMATION:**I. Table of Abbreviations**

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

**II. Background Information and
Regulatory History**

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.” 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. We must establish this safety zone as soon as possible to protect personnel, vessels, and the marine environment from potential hazards created by the fireworks displays beginning June 26, 2025. Therefore, publication of an NPRM is impracticable as the Coast Guard does not have sufficient time to receive, consider, and respond to comments before the series of fireworks displays begins.

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 immediate action is needed to respond to the potential safety hazards associated with fireworks launched from a barge in the waters of the Laguna Madre.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Corpus Christi (COTP) has determined that potential hazards associated with a fireworks display will be a safety concern for anyone within an 800-foot radius from a stationary barge from which the fireworks will be launched. The purpose of this rule is to ensure safety of vessels and persons on these navigable waters in the safety zone while the display of the fireworks takes place in the Laguna Madre.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from June 26, 2025, through July 30, 2025. The safety zone will be subject to enforcement from the hours of 9 p.m. through 11:59 p.m. each day it is in effect. It is anticipated that fireworks will only take place on each of the following nights: June 27; July 1, 8, 11, 15, 18, 22, 25, and 29. The COTP or a designated representative will inform the public of the enforcement times and dates for this safety zone through Broadcast Notices to Mariners and Safety Marine Information Broadcasts, as appropriate. The safety zone will encompass certain navigable waters of the Laguna Madre and is defined by an 800-foot radius around the launching platform. The regulated area encompasses an 800-foot radius around the following point: 26°6′02.1″

N, 97°10′17.7″ W. No vessel or person is permitted to enter the temporary safety zone during the effective period without obtaining permission from the COTP or a designated representative, who may be contacted on Channel 16 VHF–FM (156.8 MHz) or by telephone at 361–939–0450.

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.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) has not designated this rule a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it.

The regulatory action determination is based on the size, location, and duration of the safety zone. It is anticipated that the temporary safety zone will only be subject to enforcement for a short period (3 hours) each of several nights in June and July 2025. The zone is limited to an 800-foot radius of the launching position in the navigable waters of the Laguna Madre. Vessels will be able to transit around the safety zone unobstructed, and mariners may also be permitted to enter or transit through the zone when the COTP or their representative determines it is safe to do so.

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 safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule establishes a temporary safety zone for navigable waters of the Laguna Madre in a zone defined by an 800-foot radius around the following coordinate: 26°6′02.1″ N, 97°10′17.7″ W. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by fireworks displays in the waters of the Laguna Madre, and will be enforced approximately three hours per night, for several nights in June and July 2025. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

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. 01.4.

■ 2. Add § 165.T08–0462 to read as follows:

§ 165.T08–0462 Safety Zone; Laguna Madre, South Padre Island, TX.

(a) *Location.* The following area is a safety zone: all navigable waters of the Laguna Madre encompassed by an 800-foot radius around the following point: 26°6′02.1″ N, 97°10′17.7″ W.

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

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

(2) To seek permission to enter, contact the COTP or the COTP's representative on Channel 16 VHF–FM (156.8 MHz) or by telephone at 361–939–0450. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(d) *Enforcement period.* This section will be enforced from 9 p.m. through 11:59 p.m. on June 27; and July 1, 8, 11, 15, 18, 22, 25, and 29. The COTP or a designated representative will inform the public of the enforcement times and dates for this safety zone through Broadcast Notices to Mariners and Safety Marine Information Broadcasts.

Dated: June 25, 2025.

Torrey H. Bertheau,

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

[FR Doc. 2025–12366 Filed 7–1–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2025–0570]

Safety Zones; Recurring Safety Zones in Captain of the Port Northern Great Lakes Zone

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce various safety zones for maritime events in the Captain of the Port Northern Great Lakes zone. Enforcement of these safety zones is necessary to protect the safety of life and property on the navigable waters immediately prior to, during, and immediately after these events. During each enforcement period, the Coast Guard will enforce restrictions upon, and control movement of, vessels in the specified areas immediately prior to, during, and immediately after events. During each enforcement period, no person or vessel may enter the respective safety zone without permission of the Captain of the Port Northern Great Lakes or his designated representative.

DATES: The regulations in 33 CFR 165.918 will be enforced for the safety zones for the events on the dates and times specified in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: If you have questions about this publication, call or email Waterways Management division, LT Rebecca Simpson, Coast Guard Sector Northern Great Lakes, U.S. Coast Guard; telephone 906–635–3223, email ssmprevention@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones listed in 33 CFR 165.918, Table 165.918, at the following dates and times for the following events:

Canada Day Celebration Fireworks, Sault Sainte Marie, MI: The safety zone listed in Table 165.918, event (7), will be enforced from 10 p.m. through 11 p.m. on July 1, 2025.

Marquette Fourth of July Celebration Fireworks, Marquette, MI: The safety zone listed in Table 165.918, event (8), will be enforced from 10 p.m. through 10:30 p.m. on July 3, 2025. In the case of inclement weather on July 3, 2025, this safety zone will be enforced from 10 p.m. through 10:30 p.m. on July 4, 2025.

Munising Fourth of July Celebration Fireworks, Munising, MI: The safety zone listed in Table 165.918, event (9), will be enforced from 7 p.m. through 11:45 p.m. on July 4, 2025.

Sault Sainte Marie Fourth of July Celebration Fireworks, Sault Sainte Marie, MI: The safety zone listed in Table 165.918, event (10), will be enforced from 10 p.m. through 10:30 p.m. on July 4, 2025. In the case of inclement weather on July 4, 2025, this safety zone will be enforced from 10 p.m. through 10:30 p.m. on July 5, 2025.

Mackinac Island Fourth of July Celebration Fireworks, Mackinac Island,

MI: The safety zone listed in Table 165.918, event (11), will be enforced from 9:30 p.m. through 11 p.m. on July 4, 2025. In the case of inclement weather on July 4, 2025, this safety zone will be enforced from 10 p.m. through 10:30 p.m. on July 5, 2025.

Harbor Springs Fourth of July Celebration Fireworks, Harbor Springs, MI: The safety zone listed in Table 165.918, event (12), will be enforced from 10 p.m. through 11 p.m. on July 4, 2025. In the case of inclement weather on July 4, 2025, this safety zone will be enforced from 10 p.m. through 10:30 p.m. on July 5, 2025.

Bay Harbor Yacht Club Fourth of July Celebration Fireworks, Petoskey, MI: The safety zone listed in Table 165.918, event (13), will be enforced from 10 p.m. through 11:30 p.m. on July 3, 2025.

Petoskey Fourth of July Celebration Fireworks, Petoskey, MI: The safety zone listed in Table 165.918, event (14), will be enforced from 10 p.m. through 11 p.m. on July 4, 2025.

Boyne City Fourth of July Celebration Fireworks, Boyne City, MI: The safety zone listed in Table 165.918, event (15), will be enforced from 09:30 p.m. through 11 p.m. on July 4, 2025.

Alpena Fourth of July Celebration Fireworks, Alpena, MI: The safety zone listed in Table 165.918, event (16), will be enforced from 10 p.m. through 11 p.m.

Traverse City Fourth of July Celebration Fireworks, Traverse City, MI: The safety zone listed in Table 165.918, event (17), will be enforced from 10 p.m. through 11 p.m. on July 4, 2025. In the case of inclement weather on July 4, 2025, this safety zone will be enforced from 10 p.m. through 10:30 p.m. on July 5, 2025.

Charlevoix Venetian Festival Friday Night Fireworks, Charlevoix, MI: The safety zone listed in Table 165.918, event (18), will be enforced from 10 p.m. through 10:30 p.m. on July 25, 2025.

Charlevoix Venetian Saturday Night Fireworks, Charlevoix, MI: The safety zone listed in Table 165.918, event (19), will be enforced from 10 p.m. through 10:30 p.m. on July 26, 2025.

Elk Rapids Harbor Days Fireworks, Elk Rapids, MI: The safety zone listed in Table 165.918, event (20), will be enforced from 10 p.m. through 10:30 p.m. on August 2, 2025.

Nautical City Fireworks, Rogers City, MI: The safety zone listed in Table 165.918, event (21), will be enforced from 10 p.m. through 10:30 p.m. on August 3, 2025.

The locations for these events are in Table 165.918. Under the provisions of § 165.918, entry into, transiting, or

anchoring within any of the safety zones is prohibited unless authorized by the Captain of the Port Northern Great Lakes or his designated representative. Vessels that wish to transit through the safety zones may request permission from the Captain of the Port Northern Great Lakes or his designated representative.

Requests must be made in advance and approved by the Captain of Port Northern Great Lakes before transits will be authorized. Approval will be granted on a case-by-case basis. The Captain of the Port Northern Great Lakes may be contacted via U.S. Coast Guard Sector Northern Great Lakes on channel 16, VHF-FM or by calling (906) 635-3236. The Coast Guard will give notice to the public via VHF radio broadcasts that the regulation is in effect.

This notice of enforcement is issued under authority of 33 CFR 165.918 and 5 U.S.C. 552(a). If the Captain of the Port Northern Great Lakes determines that any of these safety zones need not be enforced for the full duration stated in this notice, he may suspend such enforcement and notify the public of the suspension via a Broadcast Notice to Mariners.

Dated: June 27, 2025.

J.R. Bendle,

Captain, U.S. Coast Guard, Captain of the Port Sector Northern Great Lakes.

[FR Doc. 2025-12335 Filed 7-1-25; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 9

Servicemembers' Group Life Insurance and Veterans' Group Life Insurance

CFR Correction

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

■ In Title 38 of the Code of Federal Regulations, Parts 0 to 17, revised as of July 1, 2024, in section 9.1, paragraph (k)(2) is reinstated to read as follows:

§ 9.1 Definitions.

* * * * *

(k) * * *

* * * * *

(2) The term does not include any fetus or child extracted for purposes of an abortion.

* * * * *

[FR Doc. 2025-12352 Filed 7-1-25; 8:45 am]

BILLING CODE 0099-10-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 59

[EPA-HQ-OAR-2006-0971; FRL-12710-01-OAR]

RIN 2060-AW62

National Volatile Organic Compound Emission Standards for Aerosol Coatings: Interim Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim Final Rule; request for comment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is taking interim final action to revise the compliance deadline in recent amendments to the National Volatile Organic Compound Emission Standards for Aerosol Coatings under Clean Air Act (CAA) section 183(e). Specifically, the EPA is revising the compliance date for requirements amended in January 17, 2025, from July 17, 2025, to January 17, 2027. The EPA seeks comments on this targeted revision to the compliance date and will respond and update this interim final action as appropriate.

DATES: This rule is effective on July 2, 2025. Comments on this rule must be received on or before August 1, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2006-0971 by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov> (our preferred method). Follow the online instructions for submitting comments.

- *Email:* a-and-r-docket@epa.gov. Include Docket ID No. EPA-HQ-OAR-2006-0971 in the subject line of the message.

- *Fax:* (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2006-0971.

- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2006-0971, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

- *Hand/Courier Delivery:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.-4:30 p.m., Monday-Friday (except Federal holidays).

Instructions. All submissions received must include the Docket ID No. EPA-HQ-OAR-2006-0971 for this rulemaking. Comments received may be posted without change to <https://>

www.regulations.gov, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For information about the National Volatile Organic Compound Emission Standards for Aerosol Coatings, contact Kaye Whitfield, U.S. EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Minerals and Manufacturing Group (D243-02), 109 T.W. Alexander Drive, P.O. Box 12055, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-2509; and email address: whitfield.kaye@epa.gov.

SUPPLEMENTARY INFORMATION:

Public Participation. Submit your written comments, identified by Docket ID No. EPA-HQ-OAR-2006-0971 at <https://www.regulations.gov> (our preferred method) or by the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to the EPA's docket at <https://www.regulations.gov> any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. This type of information should be submitted as discussed in the *Submitting CBI* section of this document. Multimedia submissions (audio, video, *etc.*) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). Please visit <https://www.epa.gov/dockets/commenting-epa-dockets> for additional submission methods; the full EPA public comment policy; information about CBI or multimedia submissions; and general guidance on making effective comments.

Submitting CBI. Do not submit information containing CBI to the EPA through <https://www.regulations.gov>. Clearly mark the part or all the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, note the docket ID, mark the outside of the digital storage media as CBI, and identify electronically within the digital storage media the specific information

that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in the *Public Participation* section of this document. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI and note the docket ID. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

Our preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol (FTP), or other online file sharing services (*e.g.*, Dropbox, OneDrive, Google Drive). Electronic submissions must be transmitted directly to the Office of Air Quality Planning and Standards (OAQPS) CBI Office at the email address oaqpschi@epa.gov, and as described above, should include clear CBI markings and note the docket ID. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email oaqpschi@epa.gov to request a file transfer link. If sending CBI information through the U.S. Postal Service, please send it to the following address: OAQPS Document Control Officer (C404-02), OAQPS, U.S. Environmental Protection Agency, 109 T.W. Alexander Drive, P.O. Box 12055, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2006-0971. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

Preamble acronyms and abbreviations. Throughout this document the use of "we," "us," or "our" is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

APA Administrative Procedure Act
ACA American Coatings Association
CAA Clean Air Act
CBI Confidential Business Information
CFAR Coalition for Fair Aerosol Regulation
CFR Code of Federal Regulations
CRA Congressional Review Act

EPA Environmental Protection Agency
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PRA Paperwork Reduction Act
RF Reactivity Factor
RFA Regulatory Flexibility Act
UMRA Unfunded Mandates Reform Act

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

- I. General Information
 - A. Potentially Affected Entities
 - B. Statutory Authority
 - C. Judicial Review and Administrative Review
- II. Regulatory Revisions
 - A. Background and Summary
 - B. Specific Regulatory Revisions
- III. Rulemaking Procedures
- IV. Request for Comment
- V. Statutory and Executive Order Reviews
 - A. Executive Orders 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
 - B. Executive Order 14192: Unleashing Prosperity Through Deregulation
 - C. Paperwork Reduction Act (PRA)
 - D. Regulatory Flexibility Act (RFA)
 - E. Unfunded Mandates Reform Act (UMRA)
 - F. Executive Order 13132: Federalism
 - G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
 - H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
 - I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
 - J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51
 - K. Congressional Review Act (CRA)

I. General Information

A. Potentially Affected Entities

The entities potentially affected by this regulation encompass those engaged in many aspects of the manufacture and sale of aerosol coatings. This includes manufacturers, processors, wholesale distributors, or importers of aerosol coating products for sale or distribution in interstate commerce in the United States, or manufacturers, processors, wholesale distributors, or importers who supply the entities listed above with aerosol coatings for sale or distribution in interstate commerce in the United States. In addition, affected entities include those listed in the 2022 North American Industry Classification System codes 325510 and 325998. This list is not intended to be exhaustive but rather provides a guide for entities

likely to be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the appropriate EPA contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

B. Statutory Authority

The statutory authority to issue the amendments finalized in this action is provided by the same CAA provisions that authorized the EPA to promulgate the regulations being amended: CAA sections 114 and 183b(e), 42 U.S.C. 7414, 7511b(e). Statutory authority for the rulemaking procedures followed in this action is provided by Administrative Procedure Act (APA) section 533b(B), 5 U.S.C. 533b(B).

C. Judicial Review and Administrative Review

Under CAA section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by September 2, 2025. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

II. Regulatory Revisions

A. Background and Summary

The EPA initially promulgated the “National Volatile Organic Compound Emission Standards for Aerosol Coatings” (aerosol coatings rule) on March 24, 2008 (73 FR 15604), and codified the action at 40 CFR part 59, subpart E (sections 59.500–59.516). The rule establishes nationwide VOC reactivity-based standards for the aerosol coatings source category under CAA section 183(e). As relevant here, CAA section 183(e) requires the EPA to control VOC emissions from certain categories of consumer and commercial products for purposes of reducing VOC emissions that contribute to ozone formation and nonattainment of the ozone national ambient air quality standards.

The EPA has amended the original aerosol coatings rule several times to respond to petitions and to make rule clarifications. Many of the amendments were made pursuant to a provision in 40 CFR 59.511(j) that allows regulated entities that elect against using the default reactivity factors (RF) to calculate product-weighted reactivity (PWR) limits to “petition the Administrator to add a compound to Table 2A, 2B, or 2C of this subpart.”

Such petitions “must include the chemical name, CAS number, a statement certifying the intent to use the compound in an aerosol coatings product, and adequate information for the Administrator to evaluate the reactivity of the compound and assign a RF. . . .” Through this process, the EPA amended the aerosol coatings rule to move the applicability and initial compliance date for aerosol coatings, as specified in 40 CFR 59.501(c) and 59.502(a), from January 1, 2009, to July 1, 2009, and to require initial notification reports under 40 CFR 59.501(f)(3)(i), 59.511(b), and 59.511(e), to be due on the compliance date rather than 90 days in advance of the compliance date (73 FR 78994); and to add 131 compounds, corresponding RFs, and CAS numbers for each compound or class of compounds listed in 40 CFR part 59, table 2 (79 FR 29604).

As for rule clarifications, the EPA has made revisions that clarify which VOC are to be quantified in compliance determinations (79 FR 29604); to inform regulated entities that VOC normally exempt by definition under 40 CFR 51.100(s)(1) and (s)(5) must nevertheless be counted as VOC for the purposes of determining compliance with the aerosol coatings rule (74 FR 29595); and to ensure that both the certifying entity and the regulated entity have full knowledge of responsibilities assumed by the certifying entity (74 FR 29595).

Most recently, on January 17, 2025, in response to petitions from the American Coatings Association (ACA), the EPA finalized amendments to the aerosol coatings rule that promoted consistency and uniformity, as appropriate, between the California Air Resources Board (CARB) Regulation for Reducing Ozone Formed from Aerosol Coating Product Emissions and the national aerosol coatings rule (90 FR 5697). In the January 17, 2015, final action, the EPA set a compliance date of July 17, 2025, for the amendments to the national aerosol coatings rule, based upon the Agency’s then understanding of the lead time regulated entities would need to take actions to comply. Although some commenters had requested a later compliance date, the EPA did not have factual information to justify a later compliance date at that time. However, in response to commenters, the EPA made the effective date for the amendments to be the date of publication, *i.e.*, January 17, 2025, for the benefit of regulated entities that elect to comply with the amended requirements of the aerosol coatings rule voluntarily in advance.

Following the issuance of the final rule, certain regulated entities expressed

concern about the July 17, 2025, compliance date. On March 3, 2025, ACA sent a letter on behalf of its members notifying the EPA that it is not possible for some aerosol coatings manufacturers to comply with the amended rule by the current July 17, 2025, compliance date. On March 18, 2025, the EPA received a petition for review, reconsideration, and stay of the final rule from the Coalition for Fair Aerosol Regulation (CFAR) and Diamond Vogel, Inc. These Petitioners provided additional information supporting the need for additional time for compliance by certain regulated entities. Specifically, the Petitioners contend that significantly more time is required to reformulate, relabel, and communicate with suppliers, customers, and distributors. Petitioner Diamond Vogel indicated that it and its customers manufacture and package many different aerosol coatings products that will require reformulation and that this can be challenging and time consuming. In addition, the petitioner explained that it will need to undertake these actions for multiple products for itself and multiple customers simultaneously. The petitioner stated its belief that it will be able to reformulate the existing aerosol coatings products, but that this will require substantially more time. The CFAR and Diamond Vogel petition for reconsideration is in the docket for this action. This more detailed information concerning the time need for regulated entities to comply was not available to the EPA during the rulemaking for the January 17, 2025, amendments to the aerosol coatings rule.

After evaluation of the additional information, the EPA granted the petition for reconsideration by a letter dated April 3, 2025. In this interim final action, the EPA is changing the compliance date for the amendments to the aerosol coatings rule from July 17, 2025, to January 17, 2027.

B. Specific Regulatory Revisions

The regulatory revisions necessary to change the compliance dates associated with the standards in this rule (40 CFR part 59, subpart E) to January 17, 2027, are to amend 40 CFR 59.502 by revising paragraphs (a) and (d); 40 CFR 59.505 by revising paragraph (h); 40 CFR 59.509 by revising paragraph (g); 40 CFR 59.511 by revising paragraph (k); and 40 CFR 59.512 by revising paragraph (b), and to revise appendix A to subpart E of part 59. In addition, we are revising the titles in appendix A to subpart E of part 59, including table 1, table 2A, table 2B, table 2C, and table 3.

III. Rulemaking Procedures

As noted in section I.C. of this document, the EPA's authority for the rulemaking procedures followed in this action is provided by APA section 553(b)(B). This provision authorizes agencies to forego prior notice and comment "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons, therefore, in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."

The EPA finds good cause to issue this notice without prior notice and comment because such procedures are impracticable. Specifically, there is insufficient time before the July 17, 2025, compliance date to address the new information submitted by Petitioners on compliance difficulties absent immediate action. The January 17, 2025, amendments to the aerosol coatings rule impose revised regulatory requirements on regulated entities. Although the information then available to the EPA indicated that the July 17, 2025, compliance date would provide sufficient time for regulated entities to comply with the amendments, the Agency subsequently received additional information concerning the time needed for compliance for many regulated entities. Specifically, information provided in the March 18, 2025 petition for reconsideration submitted by CFAR and Diamond Vogel, Inc. explains in detail the need for additional time for some regulated entities to reformulate products, to relabel containers, and to communicate changes with suppliers, customers, and distributors. This additional information provided by the Petitioners supports the need for extending the compliance date.

The compliance date is a significant element of any regulation, especially one that may require regulated entities to undertake time-consuming changes to products like aerosol coatings. Regulated entities may need significant time to initiate changes in advance of a compliance date given the interrelated steps discussed above. Because of the imminent July 17, 2025 compliance date, the EPA has determined that it would be impracticable to undertake prior notice and comment in the time available to provide regulated entities sufficient time to comply without unavoidable adverse consequences or potential inadvertent violations of the amended requirements.

The EPA has concluded based on information provided in the petition referenced above that meaningful compliance by some regulated entities

will not be possible by the existing compliance deadline. This information was not available to the EPA in relevant part when it set the existing compliance deadline for the amendments to the aerosol coatings rule of July 17, 2025, and the existing compliance deadline does not meaningfully take these challenges into account. Under these circumstances, refraining from amending the compliance deadline before it goes into effect would needlessly put many regulated entities out of compliance and ultimately jeopardize the EPA's ability to work with regulated entities to achieve the protective outcomes envisioned in the aerosol coatings rule.

For the reasons discussed earlier in this document, this interim final rule is effective immediately upon publication. APA section 553(d) provides that final rules may become effective upon publication in the **Federal Register** if the rule "relieves a restriction," is an interpretive rule or statement of policy, or if the agency otherwise finds "good cause" for doing so. 5 U.S.C. 553(d)(1)–(3). The purpose of this provision is "to give affected parties a reasonable time to adjust their behavior before the final rule takes effect." *Omnipoint Corp. v. FCC*, 78 F.3d 620, 630 (D.C. Cir. 1996). In determining whether good cause exists to waive the 30-day delay, an agency should "balance the necessity for immediate implementation against principles of fundamental fairness which require all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling." *Id.* (citing *United States v. Gavrilovic*, 551 F.2d 1099, 1105 (8th Cir. 1977)). The EPA has determined that there is good cause for making this final rule effective immediately under section 553(d) because it relieves obligations to achieve full compliance with the amended aerosol coating rule by the existing deadline. As such, regulated parties do not require additional time to adjust their behavior before this final rule goes into effect. For the same reasons, the rule also "relieves a restriction" under section 553(d)(1).

IV. Request for Comment

As explained in section III of this document, the EPA finds good cause to take this interim final action without prior notice or opportunity for public comment. However, the EPA is providing an opportunity for comment on extension of the compliance date for the amendments to the aerosol coating rule finalized on January 17, 2025, and requests comment on the revisions described in this rule. The EPA is not reopening for comment any provisions

of the aerosol coatings final rule amendments other than the specific provisions that are expressly amended in this interim final rule. The EPA will review and respond to any comments received, including by making changes to this action if appropriate.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Orders 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review. In the amendments to the aerosol coatings final rule (90 FR 5697), the Agency estimated that there are no adverse economic impacts anticipated from compliance with that rule. However, Petitioners have requested that the Agency delay the compliance date from July 17, 2025, to January 17, 2027, suggesting that the revised compliance date may lead to a reduction in burden. Delaying the compliance date until January 17, 2027, could result in cost savings for any regulated entity that needs to reformulate their products and adapt their distribution methods to implement the requirements of the amendments in the final rule.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is considered an Executive Order 14192 deregulatory action. This final rule provides burden reduction by delaying the compliance date to allow regulated entities additional time to come into compliance.

C. Paperwork Reduction Act (PRA)

The information collection does not impose any new information collection burden under the PRA. The Office of Management and Budget (OMB) has previously approved the information collection activities that apply to the regulated entities affected by this action and has assigned OMB control number 2060–0617. This action does not change the information collection requirements.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The EPA concludes that this rule will not have a significant

economic impact on a substantial number of small entities because the rule has no net increase in burden on the small entities subject to the rule.

E. Unfunded Mandates Reform Act (UMRA)

This final action does not contain an unfunded mandate of \$100 million as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or the private sector. This rule extends the deadline for compliance from July 17, 2025, to January 17, 2027.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have Tribal implications as specified in Executive Order 13175. The rule will extend the deadline for compliance for regulated entities from July 17, 2025, to January 17, 2027. It does not have a substantial direct effect on one or more Indian Tribes, in that this action imposes no regulatory burdens on Tribes. Thus, Executive Order 13175 does not apply to this action.

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

Executive Order 13045 directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because it is not a significant regulatory action under section (3)(f)(1) of Executive Order 12866 and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

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

This action is not subject to Executive Order 13211 because it is not a

significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action does not involve technical standards; therefore, the NTTAA does not apply.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801–808, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States.

List of Subjects in 40 CFR Part 59

Environmental protection, Administrative practice and procedure, Aerosol coatings, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Lee Zeldin,
Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 59 of title 40 of the Code of Federal Regulations as follows:

PART 59—NATIONAL VOLATILE ORGANIC COMPOUND EMISSION STANDARDS FOR CONSUMER AND COMMERCIAL PRODUCTS

- 1. The authority citation for part 59 continues to read as follows:

Authority: 42 U.S.C. 7414 and 7511b(e).

Subpart E—National Volatile Organic Compound Emission Standards for Aerosol Coatings

- 2. Amend § 59.502 by revising paragraphs (a) and (d) to read as follows:

§ 59.502 When do I have to comply with this subpart?

(a) Except as provided in § 59.509 and paragraphs (b) and (c) of this section, you must be in compliance with all provisions of this subpart by January 17, 2027.

* * * * *

(d) Until January 17, 2027, appendix A—table 1, appendix A—table 2A, appendix A—table 2B, appendix A—table 2C and the test methods listed in appendix A table 3 to subpart E of part 59 are applicable to this subpart. Prior to January 17, 2027, regulated entities may elect to use tables 1, 2A, 2B, and 2C. If a regulated entity elects to do so, it shall use the test methods specified in § 59.508 of this subpart. After January 17, 2027, tables 1, 2A, 2B, and 2C, and the test methods specified in § 59.508 of this subpart are applicable.

- 3. Amend § 59.505 by revising paragraph (h) to read as follows:

§ 59.505 How do I demonstrate compliance with the reactivity limits?

* * * * *

(h) Until January 17, 2027, the test methods listed in table 3 of appendix A to subpart E of part 59 are applicable to this subpart.

- 4. Amend § 59.509 by revising paragraph (g) to read as follows:

§ 59.509 Can I get a variance?

* * * * *

(g) Beginning on January 17, 2027, or once the notification/report template for this subpart has been available on the CEDRI website for six months, whichever date is later, submit the request for a variance with the information in paragraphs (a)(1) through (6) following the procedure specified in § 59.511(l).

- 5. Amend § 59.511 by revising paragraph (k) to read as follows:

§ 59.511 What notifications and reports must I submit?

* * * * *

(k) Beginning on January 17, 2027, or once the notification/report template for this subpart has been available on the CEDRI website for six months, whichever date is later, regulated entities shall submit all notifications, reports, and other information required in paragraphs (b) through (j) of this section following the procedure specified in paragraph (l) of this section.

* * * * *

- 6. Amend § 59.512 by revising paragraph (b) to read as follows:

§ 59.512 Addresses of EPA Regional Offices.

* * * * *

(b) Beginning on January 17, 2027, or once the notification/report template for this subpart has been available on the CEDRI website for six months, whichever date is later, regulated entities shall submit all notifications, reports, and other information required in § 59.511(b) through (j) following the procedure specified in § 59.511(l).

- 7. Revise the heading of appendix A to subpart E of part 59 to read as follows:

Appendix A to Subpart E of Part 59—In compliance with 40 CFR Part 59, Subpart E, the following standards will remain applicable prior to January 17, 2027.

- 8. Revise the heading of appendix A—table 1 to subpart E of part 59 to read as follows:

Appendix A—Table 1 to Subpart E of Part 59—Product-Weighted Reactivity Limits by Coating Category Applicable Prior to January 17, 2027

* * * * *

■ 9. Revise the heading of appendix A—table 2A to subpart E of part 59 to read as follows:

Appendix A—Table 2A to Subpart E of Part 59—Reactivity Factors—Applicable Prior to January 17, 2027

* * * * *

■ 10. Revise the heading of appendix A—table 2B to subpart E of part 59 to read as follows:

Appendix A—Table 2B to Subpart E of Part 59—Reactivity Factors for Aliphatic Hydrocarbon Solvent Mixtures—Applicable Prior to January 17, 2027

* * * * *

■ 11. Revise the heading of appendix A—table 2C to subpart E of part 59 to read as follows:

Appendix A—Table 2C to Subpart E of Part 59—Reactivity Factors for Aromatic Hydrocarbon Solvent Mixtures—Applicable Prior to January 17, 2027

* * * * *

■ 12. Revise the heading of appendix A—table 3 to subpart E of part 59 to read as follows:

Appendix A—Table 3 to Subpart E of Part 59—Methods—Applicable Prior to January 17, 2027

* * * * *

[FR Doc. 2025-12323 Filed 7-1-25; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 571 and 572

[Docket No. NHTSA-2025-0046]

RIN 2127-AM62

Federal Motor Vehicle Safety Standard No. 213a; Child Restraint Systems—Side Impact Protection; Federal Motor Vehicle Safety Standard No. 213; Child Restraint Systems, Federal Motor Vehicle Safety Standard No. 213b; Child Restraint Systems

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of enforcement discretion.

SUMMARY: This notice announces that NHTSA will not take enforcement action against regulated entities for failing to comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 213a, Child restraint systems—side impact protection until the publication of any final rule finalizing NHTSA's May 30, 2025 proposal.

DATES: This notice of enforcement discretion is effective from June 30, 2025, until the date of publication of any rule finalizing NHTSA's May 30, 2025 proposal.

FOR FURTHER INFORMATION CONTACT: For technical issues, you may contact Cristina Echemendia, Office of Crashworthiness Standards (email: Cristina.Echemendia@dot.gov). For legal issues, you may contact John Piazza, Office of Chief Counsel (email: John.Piazza@dot.gov). You can reach these officials by phone at 202-366-1810. Address: National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Washington, DC 20590.

Electronic Access and Filing: This document, the notice of proposed rulemaking (NPRM), all comments received, and all background material may be viewed online at www.regulations.gov using the docket number listed above. Electronic retrieval help and guidelines are available on the website. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at www.federalregister.gov and the Government Publishing Office's website at www.Govinfo.gov.

SUPPLEMENTARY INFORMATION:

Background

On June 30, 2022, NHTSA published a new side impact standard, FMVSS No. 213a, “Child restraint systems—side impact protection.”¹ NHTSA set a compliance date of June 30, 2025, when issuing this standard. On May 30, 2025, NHTSA published a notice of proposed rulemaking (NPRM) to amend the agency's safety standards for child restraint systems (CRSs), including FMVSS No. 213a.² The comment period for the NPRM closes on June 30, 2025.

The NPRM included, among other things, two proposals regarding compliance with the new side impact standard, FMVSS No. 213a; Child restraint systems—side impact protection. First, NHTSA proposed to exempt certain CRSs manufactured exclusively for use on school buses from

FMVSS No. 213a. In the NPRM, NHTSA explained that while the side impact standard currently exempts harnesses and car beds, it does not currently exempt school bus child restraints that are not harnesses. NHTSA also proposed to exempt school bus CRSs that are not harnesses from the standard because it tentatively believed that it is not practicable for these CRSs to meet the proposed requirements and because they serve a niche market not currently met by other types of CRSs. NHTSA also recognized that the side impact crash environment of a school bus differs significantly from the simulated side impact test in FMVSS No. 213a.³

Second, in the NPRM, NHTSA proposed to delay the compliance date for FMVSS No. 213a from June 30, 2025 to December 5, 2026.⁴ In the proposal, NHTSA considered this delay warranted for several reasons. The side impact standard is new and broadly applicable, meaning CRS manufacturers must certify most, if not all, of their products to a variety of new requirements. The agency understands this takes a significant amount of testing for research, development, and certification. Such increased demand limits some manufacturers' access to test facilities, further complicating their ability to prepare to certify to a new standard.

In the proposal, NHTSA considered the new standard still capable of significant safety benefits in the long term, but the near-term inability of some manufacturers to complete the development of compliant seats in time could create new safety problems by reducing the availability of new CRSs. Information received from some CRS manufacturers and other stakeholders, such as in comments received thus far to the NPRM and in a petition for reconsideration that predated the NPRM, indicate that the current compliance date of June 30, 2025 will likely reduce the availability of new CRSs in the market. This is because some manufacturers may have no option other than to cease manufacturing CRSs because they cannot comply with the side impact standard by June 30, 2025.

In the proposal, NHTSA expressed concern about the overall safety effects if some consumers lose access to these safety devices in the future due to limits on the availability of new CRSs. The safety consequences of reduced

³ For a more detailed discussion of this and the proposed amendment to the compliance date discussed below, please see the NPRM.

⁴ The proposed revised compliance date of December 5, 2026, would coincide with the compliance date for the FMVSS No. 213b companion upgrade of the CRS standards.

¹ 87 FR 39234.

² 90 FR 23009.

availability of CRSs can be mitigated if manufacturers have more time to test and certify their applicable products to the side impact standard to ensure currently compliant CRSs remain available on the market. Moreover, for school bus CRSs, the current compliance date may result in requirements being imposed for a short period of time, given that the agency is engaged in a rulemaking proceeding that proposes to exempt those devices from the standard.

Statement of Temporary Enforcement Policy

NHTSA recognizes that because the date on which the comment period closes is the same as the compliance date for FMVSS No. 213a, it will not be possible to publish a final rule prior to the current compliance date. NHTSA is concerned that the regulatory uncertainty likely to arise for the period of time in between the June 30 compliance date and any published final rule will lead to a decrease in overall levels of CRS safety as fewer CRS options are available for the public.

Considering these factors and the information available to NHTSA at this time, NHTSA believes that the public interest would be best served by NHTSA exercising its discretion to temporarily pause enforcement of the applicability of FMVSS No. 213a for CRSs produced on or after June 30, 2025, and until the date of publication of any rule finalizing NHTSA's May 30, 2025 proposal. NHTSA emphasizes, however, that under 49 U.S.C. 30115(a), a manufacturer may not certify to a standard if, in exercising reasonable care, the manufacturer has reason to know that the certification is false or misleading in a material respect. As such, even while the enforcement of the applicability of FMVSS No. 213a is paused, if a manufacturer continues to certify to the standard, the manufacturer must have a good faith basis that the CRS meets the standard. Similarly, manufacturers should not market or otherwise describe their products as meeting FMVSS No. 213a unless they are certifying to the standard. This pause affects only whether a CRS must be certified to FMVSS No. 213a, and

NHTSA intends to continue enforcement of certification to FMVSS No. 213 and FMVSS No. 213b.

The exercise of enforcement discretion herein creates no individual right of action and is not intended to bind NHTSA or otherwise establish precedent for future determinations. This temporary policy is based on the information currently before the agency. The comment period on the NPRM remains open until June 30, 2025, and NHTSA intends to carefully consider all comments received (including any late comments to the extent practicable) before issuing a final rule, if appropriate. As such, this temporary policy is intended to address the near-term safety consequences that would otherwise arise before a final rule. It does not prejudice the ultimate outcome on any of the issues within the scope of the May 30 NPRM.

Issued in Washington, DC, under authority delegated in 49 CFR 1.95, 501.4, and 501.5.

Peter Simshauser,

Chief Counsel.

[FR Doc. 2025–12311 Filed 7–1–25; 8:45 am]

BILLING CODE P

Proposed Rules

Federal Register

Vol. 90, No. 125

Wednesday, July 2, 2025

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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 52

[NRC-2025-0018]

RIN 3150-AL26

Revising the Duration of Design Certifications

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to revise the duration of design certifications (DCs). Specifically, this proposed rule would replace the 15-year duration for DCs with a 40-year duration period, both for existing DCs currently in effect and generically for future DCs, including renewals. This proposed rule would not change the date of issuance or renewal for existing DCs (*i.e.*, the start date by which an existing DC may be referenced would remain unchanged). The proposed rule would also incorporate a minor editorial correction.

DATES: Submit comments on the proposed rule by August 1, 2025. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-0018. Address questions about NRC dockets to Helen Chang; telephone: 301-415-3228; email: Helen.Chang@nrc.gov. For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION**

CONTACT section of this document.

- *Email comments to:* Rulemaking.Comments@nrc.gov. If you do not receive an automatic email reply

confirming receipt, then contact us at 301-415-1677.

- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. eastern time, Federal workdays; telephone: 301-415-1677.

You can read a plain language description of this proposed rule at <https://www.regulations.gov/docket/NRC-2025-0018>. For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Daniel Doyle, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-3748, email: Daniel.Doyle@nrc.gov; or Jordan Glisan, Office of Nuclear Reactor Regulation, telephone: 301-415-3478, email: Jordan.Glisan@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

Table of Contents:

- I. Obtaining Information and Submitting Comments
- II. Rulemaking Procedure
- III. Background
- IV. Discussion
- V. Plain Writing
- VI. Paperwork Reduction Act
- VII. Regulatory Planning and Review (Executive Order 12866)
- VIII. Availability of Documents

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2025-0018 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-0018.

- *NRC’s Agencywide Documents Access and Management System*

(ADAMS): You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the “Availability of Documents” section of this document.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

- *Technical Library:* The Technical Library, which is located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852, is open by appointment only. Interested parties may make appointments to examine documents by contacting the NRC Technical Library by email at Library.Resource@nrc.gov between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC-2025-0018 in your comment submission.

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

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

Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

Because the NRC considers this action to be non-controversial, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register**. The direct final rule will become effective on September 15, 2025. However, if the NRC receives significant adverse comments by August 1, 2025, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments in a subsequent final rule or as otherwise appropriate. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

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

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

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

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

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

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

(3) The comment causes the NRC staff to make a change (other than editorial) to the rule.

For the specific proposed changes to the NRC's regulations and additional discussion and associated analyses (including the regulatory analysis, environmental assessment, and finding of no significant impact), see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register** and at [https://](https://www.regulations.gov)

www.regulations.gov under Docket ID NRC-2025-0018.

III. Background

A standard design certification, also referred to simply as a design certification (DC), is a Commission approval by regulation of a final standard design for a nuclear power facility. A DC is codified via rulemaking and is independent of a specific site or an application to construct or operate a plant. An application to construct or operate a plant may reference a DC to take advantage of reviews previously completed by the NRC, though such an application must still address certain site-specific matters. The NRC's regulations governing DCs are codified in part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), Subpart B, "Standard Design Certifications," and specific DCs are published as appendices to part 52.

In this proposed rule, the NRC would amend its regulations to revise the duration of DCs, as approved by the Commission in Staff Requirements Memorandum (SRM)-COMDAW-24-0001, "Revising the Duration of Design Certifications," dated November 14, 2024. Specifically, this proposed rule would replace the 15-year duration period for initial DCs and renewals with a 40-year duration period, both generically and for each DC currently in effect. For DCs currently in effect, the respective date of issuance or renewal (*i.e.*, the start date by which a DC may be referenced) would remain unchanged by this proposed rule. Otherwise stated, the 40-year duration period would start upon the date of issuance or renewal of the DC.

Five DCs are currently in effect: appendix A to 10 CFR part 52, "Design Certification Rule for the U.S. Advanced Boiling Water Reactor," appendix D to 10 CFR part 52, "Design Certification Rule for the AP1000 Design," appendix E to 10 CFR part 52, "Design Certification Rule for the ESBWR Design," appendix F to 10 CFR part 52, "Design Certification Rule for the APR1400 Design," and appendix G to 10 CFR part 52, "Design Certification Rule for NuScale." Two DCs have expired because no timely renewal applications were submitted in accordance with § 52.57, "Application for renewal." These are appendix B to 10 CFR part 52, "Design Certification Rule for the System 80 + Design," and appendix C to 10 CFR part 52, "Design Certification Rule for the AP600 Design." Accordingly, this direct final rule applies to the five DCs currently in effect and does not apply to the two expired DCs.

IV. Discussion

The NRC is proposing to amend its regulations to revise the duration of DCs by replacing the 15-year duration for initial DCs and renewals with a 40-year duration period, both generically and for each DC currently in effect, as approved by the Commission in SRM-COMDAW-24-0001, "Revising the Duration of Design Certifications."¹ The NRC is proposing to revise these regulations based on lessons learned from carrying out the DC renewal process. These amendments would reduce unnecessary regulatory burden on applicants and save NRC resources without any reduction in safety or security.

As discussed in the 1989 final rule promulgating 10 CFR part 52, the 15-year duration for DCs was originally intended to allow actual operating experience with a given design to accumulate before the DC either expires or becomes eligible for renewal (54 FR 15372; April 18, 1989). However, experience has shown that the current 15-year certification period does not allow for sufficient time for such operating experience to accumulate prior to a DC either expiring or needing to be renewed to remain effective. In this situation, both the DC renewal applicant and the NRC expend resources involved with the submittal and review of a DC renewal application that does not reflect additional insights derived from the DC being referenced in the licensing context.

In addition, other existing regulations will continue to ensure that codified DCs and the plants referencing them meet safety and security requirements. With respect to generic changes to DC rules, the Commission has existing criteria under § 52.63(a)(1) for determining when it may modify, rescind, or impose new requirements on the certification information for a previously certified design. For example, one way the Commission may make changes to a DC rule is where the change is "necessary to provide adequate protection of the public health and safety or the common defense and security" (10 CFR 52.63(a)(1)(ii)). The Commission may change a DC rule either on its own motion or in response to a petition for rulemaking from any person, including design vendors, and such changes will provide for notice and opportunity for public comment (10 CFR 52.63(a)(2)(ii)). For potential plant-specific safety or security issues, the Commission may use plant-specific orders, subject to applicable issue finality provisions (*e.g.*, § 52.63(a)(4) for Tier 1 information). In addition,

licensees and applicants who reference a DC may also address potential safety or security concerns using the departure process described in the associated DC rule. That is, all DC rules are codified in appendices to part 52 and are structured such that Section VIII of the associated DC rule appendix prescribes an appropriate process for evaluating potential departures from the DC rule, including via a request for a license amendment or exemption. If NRC approval is required, the NRC would evaluate the request using its typical processes.

Accordingly, the change in duration for DCs would provide more time for a design to be referenced in a license application and more time for the design vendor to accumulate construction and actual operating experience before a design vendor would need to submit a renewal application. In addition, it would reduce unnecessary burdens with no reduction in safety or security.

Therefore, the NRC is proposing to amend its regulations to change the DC duration to 40 years generically in §§ 52.55, 52.57, and 52.61 as well as for DCs currently in effect in the applicable appendices to 10 CFR part 52.

V. Plain Writing

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

VI. Paperwork Reduction Act

This proposed rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget (OMB), approval number 3150–0151.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

VII. Regulatory Planning and Review (Executive Order 12866)

Executive Order (E.O.) 12866, as amended by E.O. 14215, provides that the Office of Information and Regulatory Affairs (OIRA) will determine whether a regulatory action is significant as defined by E.O. 12866 and will review significant regulatory actions. OIRA determined that this proposed rule is a significant regulatory action under E.O. 12866.

VIII. Availability of Documents

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

Document	ADAMS accession No./ Federal Register citation
Environmental Assessment and Finding of No Significant Impact by the U.S. Nuclear Regulatory Commission Relating to Revising the Duration of Design Certifications, dated May 2025.	ML25049A031
SRM-COMDAW-24-0001, “Revising the Duration of Design Certifications,” dated November 14, 2024	ML24319A209
Federal Register notice—Final Rule, “Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors,” dated April 18, 1989.	54 FR 15372
Federal Register notice—Final Rule, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” dated August 28, 2007.	72 FR 49352
Presidential Memorandum, “Plain Language in Government Writing,” published June 10, 1998	63 FR 31885

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at <https://www.regulations.gov> under Docket ID NRC–2025–0018.

Endnotes

¹For Appendix D to Part 52, “Design Certification Rule for the AP1000 Design,” this rule would replace the 20-year duration (rather than 15-year duration) with a 40-year duration period. The initial duration period was previously extended from 15 years to 20 years for the AP1000 design by direct final rule (86 FR 52593; September 22, 2021).

List of Subjects in 10 CFR Part 52

Administrative practice and procedure, Antitrust, Combined license, Early site permit, Emergency planning, Fees, Inspection, Issue finality, Limited work authorization, Manufacturing license, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Penalties, Reporting and recordkeeping requirements, Standard design, Standard design certification.

Dated: June 30, 2025.

For the Nuclear Regulatory Commission.

Michael King,

Acting Executive Director for Operations.

[FR Doc. 2025–12397 Filed 7–1–25; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–1350; Project Identifier MCAI–2024–00510–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all

Airbus Helicopters Model EC 155B and EC155B1 helicopters. This proposed AD was prompted by a determination that the required forces to jettison the windows exceed the maximum jettisoning effort requirements and the development of a modification of the jettisonable windows. This proposed AD would require replacement of the jettisonable windows and seals on the sliding doors and fixed panels on the left-hand and right-hand sides. This proposed AD would also require the installation of new labels. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by August 18, 2025.

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](https://www.regulations.gov). Follow the instructions for submitting comments.
- **Fax:** (202) 493–2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2025-1350; 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; phone: +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.

- You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Parkway, Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2025-1350.

FOR FURTHER INFORMATION CONTACT:

Adam Hein, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946-4116; email: adam.hein@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 using a method listed under the **ADDRESSES** section. Include “Docket No. FAA-2025-1350; Project Identifier MCAI-2024-00510-R” 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](https://www.regulations.gov), including any personal

information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Adam Hein, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590. 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 2024-0173, dated September 4, 2024 (EASA AD 2024-0173) (also referred to as the MCAI), to address an unsafe condition on Airbus Helicopters Model EC 155 B and EC 155 B1 helicopters. The MCAI states that during tests concerning jettisoning of windows on a Model EC 155 helicopter, it was identified that the required forces to jettison the windows exceed the maximum jettisoning effort requirements. The MCAI also states that Airbus Helicopters developed a modification of the jettisonable windows to address this unsafe condition. This condition, if not addressed, could lead to an inability to jettison the window(s) during an emergency, which could result in a reduced capability to evacuate helicopter occupants and consequent injury to occupants during an emergency. 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](https://www.regulations.gov) under Docket No. FAA-2025-1350.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024-0173, which specifies procedures for replacement of the jettisonable windows and seals on the sliding doors and fixed panels on the left-hand and right-hand sides. The MCAI also specifies procedure for installation of new labels on the sliding doors and fixed panels. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with 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 on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the material already described, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA 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 2024-0173 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024-0173 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 2024-0173 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 2024–0173. Material referenced in EASA AD 2024–0173 for compliance will be available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–

2025–1350 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 16

helicopters of U.S. registry. The FAA estimates the following costs to comply with this proposed AD.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace windows and seals and install labels.	48 work-hours × \$85 per hour = \$4,080	Up to \$53,553	Up to \$57,633	Up to \$922,128.

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:

Airbus Helicopters: Docket No. FAA–2025–1350; Project Identifier MCAI–2024–00510–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by August 18, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Model EC 155B and EC155B1 helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 5620, Passenger Compartment Windows; 5630, Door Windows.

(e) Unsafe Condition

This AD was prompted by a determination that the required forces to jettison the windows exceed the maximum jettisoning effort requirements and the development of a modification of the jettisonable windows. The FAA is issuing this AD to prevent the inability to jettison the window(s) during an emergency. The unsafe condition, if not addressed, could result in a reduced capability to evacuate helicopter occupants during an emergency and consequent injury to helicopter occupants.

(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 European Union Aviation Safety Agency AD 2024–0173, dated September 4, 2024 (EASA AD 2024–0173).

(h) Exceptions to EASA AD 2024–0173

(1) Where EASA AD 2024–0173 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2024–0173 refers to flight hours, this AD requires using hours time-in-service (TIS).

(3) This AD does not adopt the Remarks section of EASA AD 2024–0173.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2024–0173 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Additional Information

For more information about this AD, contact Adam Hein, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4116; email: adam.hein@faa.gov.

(l) 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 the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0173, dated September 4, 2024.

(ii) [Reserved]

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

(4) You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Parkway, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this 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-locations or email fr.inspection@nara.gov.

Issued on June 27, 2025.

Steven W. Thompson,

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

[FR Doc. 2025–12370 Filed 7–1–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–1351; Project Identifier MCAI–2024–00667–T]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., 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 Bombardier, Inc., Model BD–100–1A10 airplanes. This proposed AD was prompted by a report that some parts of horizontal stabilizer trim actuators (HSTAs) that were meant to be replaced through a required overhaul were not replaced and were instead reinstalled on the HSTAs. This proposed AD would require verification of the HSTA serial number, and, if applicable, replacement of the HSTA. This proposed AD would also prohibit the installation of affected parts under certain conditions. 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 August 18, 2025.

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–2025–1351; 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 Bombardier material identified in this proposed AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email ac.yul@aero.bombardier.com; website bombardier.com.

- 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: John Massey, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7300; email: 9-avs-nyaco-cos@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–2025–1351; Project Identifier MCAI–2024–00667–T” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the

following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to 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 John Massey, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7300; email: 9-avs-nyaco-cos@faa.gov. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF–2024–38, dated November 12, 2024 (Transport Canada AD CF–2024–38) (also referred to after this as the MCAI), to correct an unsafe condition on all Bombardier, Inc., Model BD–100–1A10 airplanes. The MCAI states that Bombardier has been advised that the overhaul required by certificate maintenance requirement (CMR) task 27–40–00–104 * was not fully completed on some units. As a result, some of the parts that were required to be replaced on the affected HSTAs as part of the overhauled task were re-installed in error. This condition, if not corrected, can lead to the failure of HSTA components, which can contribute to horizontal stabilizer surface disconnect at the actuator level and could lead to loss of continued safe flight and landing.

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–2025–1351.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed the following Bombardier material:

- Bombardier Service Bulletin 100–27–23, dated October 28, 2024;
- Bombardier Service Bulletin 350–27–014, dated October 28, 2024.

This material specifies procedures for verifying the HSTA serial number and, if applicable, corrective actions to include replacing the HSTA. These documents are distinct since they apply to different airplane configurations.

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 and material referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in

the material already described. This proposed AD would also prohibit the installation of affected parts under certain conditions.

Regarding the corrective action for certain HSTAs, as specified in Bombardier Service Bulletin 100–27–23 and 350–27–014, both dated October 28, 2024, rework of the HSTA is required by the manufacturer, since this manufacturer is the only producer of the affected part.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 982 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 2 work-hours × \$85 per hour = Up to \$170	\$0	Up to \$170	Up to \$166,940.

The FAA estimates the following costs to do any 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 ACTIONS

Labor cost	Parts cost	Cost per product
20 work-hours × \$85 per hour = \$1,700	\$53,665	\$55,365

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

Authority for This Rulemaking

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

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of

that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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:

Bombardier, Inc: Docket No. FAA–2025–1351; Project Identifier MCAI–2024–00667–T.

- (a) Comments Due Date**

The FAA must receive comments on this airworthiness directive (AD) by August 18, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Bombardier, Inc., Model BD–100–1A10 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Unsafe Condition

This AD was prompted by a report that some parts of horizontal stabilizer trim actuators (HSTAs) that were meant to be replaced through a required overhaul were not replaced and were instead reinstalled on the HSTAs. The FAA is issuing this AD to address HSTA parts that were not replaced as required. The unsafe condition, if not addressed, could result in the failure of HSTA components, which can contribute to horizontal stabilizer surface disconnect at the actuator level and could lead to loss of continued safe flight and landing.

(f) Compliance

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

(g) Records Verification and Corrective Actions

At the applicable time specified in figure 1 to paragraph (g) of this AD, do an inspection to determine the serial number of HSTA part number C47100–004 or C47100–005 in accordance with Section 2.B., Part A, of the Accomplishment Instructions of Bombardier Service Bulletin 100–27–23 or 350–27–014, both dated October 28, 2024, as applicable. A review of the airplane maintenance records is also acceptable provided the serial number of the HSTA can be conclusively determined from that review.

FIGURE 1 TO PARAGRAPH (g)—COMPLIANCE TIME FOR RECORDS VERIFICATION

HSTA total flight hours accumulated as of the effective date of this AD	Compliance time
10,000 or more	Before accumulating 14,500 total flight hours on the HSTA, or before accumulating 7,500 total flight cycles on the HSTA, or within 24 months after the effective date of this AD, whichever occurs first.
9,700 or more but less than 10,000	Before accumulating 14,500 total flight hours on the HSTA, or before accumulating 7,500 total flight cycles on the HSTA, or within 36 months after the effective date of this AD, whichever occurs first.
Less than 9,700	Before accumulating 14,500 total flight hours on the HSTA, or before accumulating 7,500 total flight cycles on the HSTA, or within 48 months after the effective date of this AD, whichever occurs first.

- (h) HSTA Replacement**

If, during the inspection or records review required by paragraph (g) of this AD, any HSTA having part number C47100–004 or C47100–005, with a serial number listed in Section 1.A. of Bombardier Service Bulletin 100–27–23 or 350–27–014, both dated October 28, 2024, as applicable is found: At the applicable time specified in figure 1 to paragraph (g) of this AD, replace the HSTA in accordance with Sections 2.C. and 2.D. of the Accomplishment Instructions of Bombardier Service Bulletin 100–27–23 or 350–27–014, both dated October 28, 2024, as applicable.
- (i) Parts Installation Limitation**

As of the effective date of this AD, no person may install, on any airplane, an HSTA, part number C47100–004 or C47100–005, with a serial number listed in Section 1.A. of Bombardier Service Bulletin 100–27–23 or 350–27–014, both dated October 28, 2024, unless the HSTA has a modification plate marked with Moog Service Bulletin C47100–27–07.
- (j) 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 (k) 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 Transport Canada; or Bombardier's Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.
- (k) Additional Information**

For more information about this AD, contact John Massey, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7300; email: 9-avs-nyaco-cos@faa.gov.
- (l) 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) Bombardier Service Bulletin 100–27–23, dated October 28, 2024.

(ii) Bombardier Service Bulletin 350–27–014, dated October 28, 2024.

(3) For Bombardier material identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email ac.yul@aero.bombardier.com; website bombardier.com.

(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-locations or email fr.inspection@nara.gov.
- Issued on June 30, 2025.

Steven W. Thompson,
Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2025–12369 Filed 7–1–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR**Employment and Training
Administration****20 CFR Parts 651, 653, 655, and 658****Wage and Hour Division****29 CFR Part 501**

[DOL Docket No. ETA–2025–0007]

RIN 1205–AC25

**Recission of Final Rule: Improving
Protections for Workers in Temporary
Agricultural Employment in the United
States****AGENCY:** Employment and Training
Administration and Wage and Hour
Division, Department of Labor.**ACTION:** Proposed rule.

SUMMARY: The Department of Labor (Department or DOL) is proposing to amend its regulations governing the certification of agricultural labor or services to be performed by temporary foreign workers in H–2A nonimmigrant status (H–2A workers) and enforcement of the contractual obligations applicable to employers of such nonimmigrant workers. This notice of proposed rulemaking (NPRM or proposed rule) that would rescind provisions contained within a final rule published by the Department on April 29, 2024, which adopted a number of unnecessary, burdensome, and costly requirements on employers. Specifically, these provisions include, but are not limited to, substantial new requirements associated with the material terms and conditions offered by employers to H–2A workers that are not commonly provided to other U.S. workers, including progressive discipline policies for cause-based employment terminations, anti-retaliation measures for certain workers engaged in self-organization and other concerted activities, and expanding the authority and scope for a State Workforce Agency (SWA) to discontinue employment services to employers, which prevents those employers from accessing the H–2A program, while eliminating employers' option to request a hearing prior to the SWA's final determination. Further, the final rule imposed extensive highly-sensitive data collection requirements on employers related to their use of foreign labor recruiters, including personal names and physical addresses abroad, as well as detailed personal information associated with all owners of the employers, operators of the place(s) of

employment, and supervisor(s) and manager(s) of workers employed under the terms of the work contract, with very limited or no practical utility to the agency's statutory decision making. A brief summary of this rulemaking can be found at www.regulations.gov by searching by the RIN: 1205–AC25.

DATES: Interested persons are invited to submit written comments on this proposed rule on or before September 2, 2025.

ADDRESSES: You may submit comments electronically by the following method: *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions on the website for submitting comments.

Instructions: Include the agency's name and docket number ETA–2025–XXXX0007 in your comments. All comments received will become a matter of public record and will be posted without change to <https://www.regulations.gov>. Please do not include any personally identifiable or confidential business information you do not want publicly disclosed.

FOR FURTHER INFORMATION CONTACT: For further information regarding 20 CFR parts 651, 653, and 658, contact Kimberly Vitelli, Administrator, Office of Workforce Investment, Employment and Training Administration, Department of Labor, Room C–4526, 200 Constitution Avenue NW, Washington, DC 20210, telephone: (202) 693–3980 (this is not a toll-free number). For further information regarding 20 CFR part 655, contact Brian Pasternak, Administrator, Office of Foreign Labor Certification, Employment and Training Administration, Department of Labor, 200 Constitution Avenue NW, Room N–5311, Washington, DC 20210, telephone: (202) 693–8200 (this is not a toll-free number). For further information regarding 29 CFR part 501, contact Daniel Navarrete, Director of the Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, Department of Labor, Room S–3018, 200 Constitution Avenue NW, Washington, DC 20210, telephone: (202) 693–0406 (this is not a toll-free number). For persons with a hearing or speech disability who need assistance to use the telephone system, please dial 711 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION:**I. Background***A. Legal Authority***1. Immigration and Nationality Act**

The Immigration and Nationality Act (INA), as amended by the Immigration

Reform and Control Act of 1986 (IRCA), establishes an “H–2A” nonimmigrant visa classification for a worker “having a residence in a foreign country which he has no intention of abandoning who is coming temporarily to the United States to perform agricultural labor or services . . . of a temporary or seasonal nature.” 8 U.S.C. 1101(a)(15)(H)(ii)(a); *see also* 8 U.S.C. 1184(c)(1) and 1188.¹ Agricultural labor or services includes the types of labor and services “defined by the Secretary of Labor in regulations,” as well as the Internal Revenue Code definition of “agricultural labor” at “section 3121(g) of title 26,” the Fair Labor Standards Act definition of “agriculture” at “section 203(f) of title 29,” and “the pressing of apples for cider on a farm” 8 U.S.C. 1101(a)(15)(H)(ii)(a).

The admission of foreign workers under this classification involves a multi-step process before several Federal agencies. A prospective H–2A employer must first apply to the Secretary of Labor (Secretary) for a certification that:

(A) there are not sufficient workers who are able, willing, and qualified, and who will be available at the time and place needed, to perform the labor or services involved in the petition, and

(B) the employment of the alien in such labor or services will not adversely affect the wages and working conditions of workers in the United States similarly employed.

8 U.S.C. 1188(a)(1). The INA prohibits the Secretary from issuing this certification—known as a “temporary labor certification”—unless both of the above referenced conditions are met and none of the conditions in 8 U.S.C. 1188(b) apply concerning strikes or lock-outs, labor certification program debarments, workers' compensation assurances, and positive recruitment.

The Secretary has delegated the authority to issue temporary agricultural labor certifications to the Assistant Secretary for Employment and Training, who in turn has delegated that authority to ETA's Office of Foreign Labor Certification (OFLC).² In addition, the Secretary has delegated to the Department's Wage and Hour Division (WHD) the responsibility under sec. 218(g)(2) of the INA, 8 U.S.C. 1188(g)(2), to assure employer compliance with the

¹ For ease of reference, sections of the INA are referred to by their corresponding section in the United States Code.

² *See* Secretary's Order 06–2010 (Oct. 20, 2010), 75 FR 66268 (Oct. 27, 2010).

terms and conditions of employment under the H-2A program.³

Once an employer obtains a temporary labor certification from DOL, it may then file a nonimmigrant visa petition with the Secretary of Homeland Security. *See* 8 U.S.C. 1184(c).⁴ If the employer's petition is approved, the foreign workers whom it seeks to employ must, generally, apply for a nonimmigrant H-2A visa at a U.S. Embassy or consulate abroad. *Id.* Finally, if the foreign worker is coming from abroad, he or she must apply to U.S. Customs and Border Protection for admission to the United States.⁵

2. Wagner-Peyser Act

The Wagner-Peyser Act of 1933 established the United States Employment Service (ES), a nationwide system to improve the functioning of the nation's labor markets by bringing together individuals seeking employment with employers seeking workers. 29 U.S.C. 49 *et seq.* Section 3(a) of the Act sets forth the basic responsibilities of the Department in the ES, which include assisting in coordinating the State public employment service offices throughout the country and in increasing their usefulness by prescribing standards for efficiency, promoting uniformity in procedures, and maintaining a system of clearing labor between the States. 29 U.S.C. 49b. The Act further authorizes the Department "to make such rules and regulations as may be necessary to carry out [its] provisions." 29 U.S.C. 49k.

Consistent with the aims of sec. 3(a), the ES system provides labor exchange services to its participants and has undergone numerous changes to align its activities with broader national workforce development policies and statutory requirements. The Workforce Innovation and Opportunity Act (Pub. L. 113-128), passed in 2014, expanded upon the previous workforce reforms in the Workforce Investment Act of 1998 and, among other things, identified the ES system as a core program in the One-Stop local delivery system, also called the American Job Center network.

In 1974, the case *National Ass'n for the Advancement of Colored People (NAACP)*, *Western Region, et al. v. Brennan et al.*, No. 2010-72, 1974 WL

229 (D.D.C. Aug. 13, 1974), resulted in a detailed court order mandating various Federal and State actions consistent with applicable law (Richey Order). The Richey Order required the Department to implement and maintain a Federal and State monitoring and advocacy system relating to farmworker ES services. In 1977 and 1980, consistent with its authority under the Wagner-Peyser Act, the Department published regulations at 20 CFR parts 651, 653, and 658 to implement the requirements of the Richey Order. Part 653 sets forth standards and procedures for providing services to migrant and seasonal farmworkers (MSFWs) and provides regulations governing the Agricultural Recruitment System (ARS), a system for interstate and intrastate agricultural job recruitment. Part 658 sets forth standards and procedures for the administrative handling of complaints alleging violations of ES regulations and of employment-related laws, the discontinuation of services provided by the ES system to employers, the review and assessment of State agency compliance with ES regulations, and the process the Department must follow if State agencies are not complying with the ES regulations.

B. Current Regulatory Framework

Since 1987, the Department has operated the H-2A temporary labor certification program under regulations promulgated pursuant to the INA. Prior to publication of a final rule in 2024, the majority of the Department's regulations governing the H-2A program were published in 2010 and many were updated in a final rule published in 2022.⁶ The standards and procedures applicable to the certification and employment of workers under the H-2A program are found in 20 CFR part 655, subpart B, and 29 CFR part 501. In addition, prior to 2015, the Department had issued special procedures for the employment of foreign workers in the herding and production of livestock on the range as well as animal shearing, commercial beekeeping, and custom combining occupations.⁷ The

Department incorporated the provisions for employment of workers in the herding and production of livestock on the range into the H-2A regulations, with modifications, in 2015.⁸ The provisions governing the employment of workers in the herding and production of livestock on the range are now codified at 20 CFR 655.200 through 655.235. In 2022, the Department amended the H-2A regulations by modifying the minimum standards and conditions of employment that employers must offer to workers, revising standards for determining the prevailing wage rate, expanding its enforcement authority to combat program abuse, and codified standards and procedures for employers that employ workers engaged in itinerant animal shearing, commercial beekeeping, and custom combining activities at 20 CFR 655.300 through 655.304.⁹ Relatedly, the regulations implementing the Wagner-Peyser Act at 20 CFR parts 651, 653, and 658 establish the ARS, through which employers can recruit U.S. workers for agricultural employment opportunities, and which prospective H-2A employers must use to recruit U.S. workers as a condition of receiving a temporary agricultural labor certification.

In 2024, the Department again amended the ES and H-2A regulations by adopting a number of new requirements associated with the material terms and conditions offered by employers to H-2A workers and workers recruited through the ARS, such as incorporating progressive discipline policies for cause-based employment terminations, anti-retaliation measures for workers engaged in concerted activities, expanding regulatory criteria and procedural requirements permitting a State Workforce Agency to discontinue

Involved in the Open Range Production of Livestock under the H-2A Program (June 14, 2011), https://wdr.doleta.gov/directives/corr_doc.cfm?docn=3044; TEGL No. 17-06, Change 1, *Special Procedures: Labor Certification Process for Employers in the Itinerant Animal Shearing Industry under the H-2A Program* (June 14, 2011), https://wdr.doleta.gov/directives/corr_doc.cfm?docn=3041; TEGL No. 33-10, *Special Procedures: Labor Certification Process for Itinerant Commercial Beekeeping Employers in the H-2A Program* (June 14, 2011), https://wdr.doleta.gov/directives/corr_doc.cfm?DOCN=3043; TEGL No. 16-06, Change 1, *Special Procedures: Labor Certification Process for Multi-State Custom Combine Owners/Operators under the H-2A Program* (June 14, 2011), https://wdr.doleta.gov/directives/corr_doc.cfm?DOCN=3040.

⁸ Final Rule, *Temporary Agricultural Employment of H-2A Foreign Workers in the Herding or Production of Livestock on the Range in the United States*, 80 FR 62958 (Oct. 16, 2015) (2015 H-2A Herder Final Rule).

⁹ 2022 H-2A Final Rule, 87 FR at 61771.

³ *See* Secretary's Order 01-2014 (Dec. 19, 2014), 79 FR 77527 (Dec. 24, 2014).

⁴ Under sec. 1517 of title XV of the Homeland Security Act of 2002, Public Law 107-296, 116 Stat. 2135, reference to the Attorney General's or other Department of Justice Official's responsibilities under sec. 1184(c) have been expressly transferred to the Secretary of Homeland Security. *See* 6 U.S.C. 202, 271(b).

⁵ *See generally* 8 U.S.C. 1225; 8 CFR part 235.

⁶ Final Rule, *Temporary Agricultural Employment of H-2A Aliens in the United States*, 75 FR 6884 (Feb. 12, 2010) (2010 H-2A Final Rule); Final Rule, *Temporary Agricultural Employment of H-2A Nonimmigrants in the United States*, 87 FR 61660 (Oct. 12, 2022) (2022 H-2A Final Rule).

⁷ *See* Training and Employment Guidance Letter (TEGL) No. 32-10, *Special Procedures: Labor Certification Process for Employers Engaged in Sheepherding and Goatherding Occupations under the H-2A Program* (June 14, 2011), https://wdr.doleta.gov/directives/corr_doc.cfm?docn=3042; TEGL No. 15-06, Change 1, *Special Procedures: Labor Certification Process for Occupations*

employment services to an employer, and imposing new data collection requirements related to the use of foreign labor recruiters and personal information associated with all owners of the employers, operators the place(s) of employment, and the supervisor(s) and manager(s) of workers employed under the terms of the work contract.¹⁰

C. Need for Rulemaking

On August 26, 2024, the United States District Court for the Southern District of Georgia issued a preliminary injunction order in the case *Kansas v. U.S. Department of Labor*, 749 F. Supp. 3d 1363 (S.D. Ga. 2024) (“*Kansas*”) prohibiting DOL from enforcing the entire 2024 H–2A Final Rule in 17 states and with respect to certain entities.¹¹ The preliminary injunction specifically prohibits DOL from enforcing the 2024 H–2A Final Rule in the states of Georgia, Kansas, South Carolina, Arkansas, Florida, Idaho, Indiana, Iowa, Louisiana, Missouri, Montana, Nebraska, North Dakota, Oklahoma, Tennessee, Texas, and Virginia, and against Miles Berry Farm and the members of the Georgia Fruit and Vegetable Growers Association as of August 26, 2024.

In addition, on November 25, 2024, the United States District Court for the Eastern District of Kentucky issued a preliminary injunction in the case of *Barton v. U.S. Department of Labor*, 757 F. Supp. 3d 766 (E.D. Ky. 2024) (“*Barton*”), enjoining and restraining the Department from implementing, enacting, enforcing, or taking any action in any manner to enforce certain provisions of the Farmworker Protection Rule in 4 additional states and with respect to certain entities.¹² This preliminary injunction applies to the Commonwealth of Kentucky and the States of Alabama, Ohio, West Virginia, and a large number of individual and association plaintiffs to this proceeding, including Richard Barton; Doug Langley; Benny Webb; Dale Seay; David DeMarcus, II; David DeMarcus, Sr.; Steve Stakelin; Agriculture Workforce Management Association, Inc. (including its shareholders and members); North Carolina Growers’ Association, Inc. (including all members of that non-profit association); Workers and Farmer Labor Association (including all members of that non-profit association); USA FARMERS, Inc. (including all members of that non-

profit association); and National Council of Agricultural Employers (including all members of that non-profit association). The *Barton* order prohibits the Department from implementing, enacting, enforcing, or taking any action in any manner to enforce the following provisions of the 2024 H–2A Final Rule: seat belt modifications to enhanced safety requirements including but not limited to 20 CFR 655.122(h)(4); any and all worker voice and empowerment provisions, and provisions allowing workers to invite and accept guests under § 655.135 and any and all parallel provisions under 29 CFR 501.4, including but not limited to 20 CFR 655.135(h), 655.135(m), and 655.135(n); updated information collection requirements including but not limited to § 655.130(a); and new minimum pay requirements including but not limited to §§ 655.120(a) and 655.122(l).

Also on November 25, 2024, the United States District Court for the Southern District of Mississippi issued a nationwide stay pursuant to 5 U.S.C. 705 in *International Fresh Produce Association v. U.S. Department of Labor*, 758 F. Supp. 3d 575 (S.D. Miss. 2024) (“*IFPA*”) staying the effective date of 20 CFR 655.135(h)(2) and (m) in the 2024 H–2A Final Rule until the conclusion of proceedings in the case, including any appellate proceedings.¹³ The additional plaintiffs in this proceeding include a broad coalition of state and national agricultural associations, including the American Farm Bureau Federation, Mississippi Farm Bureau Federation, Stone County Farm Bureau, Chamber of Commerce of the United States of America, AmericanHort, Florida Fruit & Vegetable Association, North American Blueberry Council, Texas International Produce Association, State of Mississippi, and U.S. Apple Association.

On the other hand, on May 5, 2025, the U.S. District Court for the Eastern District of North Carolina upheld the 2024 Final Rule in *North Carolina Farm Bureau Federation v. U.S. Department of Labor*, 2025 WL 1296245, --F. Supp. 3d, --- (E.D.N.C. 2025) (“*NCFBF*”). There, the court concluded that the rule was a lawful exercise of the Department’s authority under the INA, that the rule was not arbitrary and capricious, and that the rule did not conflict with other laws.

In these litigations challenging the Department’s 2024 H–2A Final Rule, three different district courts recognized that the public had a substantial interest in having agencies act within their congressionally designated authority

and concluded that many of the 2024 H–2A Final Rule provisions are contrary to specific Constitutional protections, other laws, or are arbitrary or capricious. These three courts granted the plaintiffs’ requests for preliminary relief, concluding that the plaintiffs were likely to succeed on their claims challenging various provisions of the rule and that the evidence weighs in favor of a finding of irreparable harm because, among other considerations, the costs of compliance related to the rule are nonrecoverable. Although the courts in the *Kansas* and *Barton* cases noted that “§ 1188 [of the INA] affords the DOL discretion to promulgate regulations that protect American workers from being adversely affected by the issuance of H–2A visas,” the *Barton* court, citing the *Kansas* court, when discussing those provisions the court deemed to have conflicted with the National Labor Relations Act (NLRA), affirmed that the Department “cannot create law, and the DOL cannot create rights that Congress has not. The DOL cannot make both executive rules and congressional laws.”¹⁴ For example, the *IFPA* court, when discussing the worker empowerment provisions, agreed that a plain reading of the statute does not confer a “broad grant of authority as to allow DOL to effectively provide collective action rights to H–2A workers in the name of reducing the adverse effect of the H–2A program on domestic workers” and pointed out that “the language does not support the conclusion that DOL can prescribe these kinds of rights as part of the ‘criteria for certification[.]’”¹⁵

In light of these district court decisions and the Administration’s policy (e.g., Executive Order 14192, *Unleashing Prosperity Through Deregulation*) to significantly reduce the private expenditures required to comply with Federal regulations to secure America’s economic prosperity and national security and the highest possible quality of life for each citizen, the Department has determined that the regulatory requirements and policies contained in the 2024 H–2A Final Rule must be reconsidered and proposes revisions in this NPRM. The Department concludes that the proposals outlined in this rulemaking, if adopted, would better ensure that the H–2A program’s regulatory framework is a more reasonable balance between the statute’s competing goals of providing an adequate labor supply and protecting

¹⁰ Final Rule, *Improving Protections for Workers in Temporary Agricultural Employment in the United States*, 89 FR 33898 (Apr. 29, 2024) (2024 H–2A Final Rule).

¹¹ *Kansas*, 749 F. Supp. 3d at 1383.

¹² *Barton*, 757 F. Supp. 3d at 794.

¹³ *IFPA*, 758 F. Supp. 3d at 594.

¹⁴ *Barton*, 757 F. Supp. 3d at 777.

¹⁵ *IFPA*, 758 F. Supp. 3d at 588 (citing 8 U.S.C. 1188(c)(3)(i)).

the jobs of domestic agricultural workers.

II. Discussion of Proposed Rule

A. Worker Voice and Empowerment Provisions

The Department proposes to rescind requirements added by the 2024 H–2A Final Rule that were collectively referred to in that rule as “protections for worker voice and empowerment.” Specifically, the Department proposes to: (1) rescind revisions to 20 CFR 655.135(h) and 29 CFR 501.4 that expanded activities protected from retaliation; (2) rescind 20 CFR 655.135(m) that required employers to permit workers engaged in agriculture as defined by 29 U.S.C. 203(f) of the Fair Labor Standards Act (FLSA) to designate a representative of their choosing in investigatory interviews; and (3) rescind the definitions of “labor organization” and “key service provider” added by the 2024 H–2A Final Rule at 20 CFR 655.103(b). The Department proposes to return to language at 20 CFR 655.135(h), and 29 CFR 501.4 in effect as of June 27, 2024, and remove these two definitions from 20 CFR 655.103(b).

The 2024 H–2A Final Rule created new activities that were protected from retaliation at 20 CFR 655.135(h)(1) and (2), and made parallel edits to 29 CFR 501.4(a)(1) and (2). The protected activities in § 655.135(h)(1) and 29 CFR 503.4(a)(1) were applicable to all people, regardless of whether they were engaged in agriculture as defined by the FLSA. These activities remained similar to those protected activities that had existed before the 2024 H–2A Final Rule, but made two important revisions; specifically, the 2024 H–2A Final Rule newly expressly protected (1) consultation with a key service provider on matters related to H–2A, and (2) filing a complaint, instituting, or causing to be instituted any proceeding, or testifying, assisting, or participating (or is about to testify, assist or participate) in any investigation, proceeding or hearing under or related to any applicable Federal, State, or local laws or regulations, including safety and health, employment, and labor law. The Department framed these changes as clarifications of existing rights; the Department noted that workers were already entitled to access and meet with many different key service providers to discuss or assert rights under the H–2A program without fear of retaliation under the Department’s previous regulatory framework. Similarly, the 2024 H–2A Final Rule noted that existing 20 CFR 655.135(e) already

required employers to comply with all applicable Federal, State, and local laws, and existing § 655.135(h)(1) and (5) already prohibited retaliation against workers who assert their rights under the H–2A program, and therefore the changes were only to make these rights explicit.

However, the protected activities implemented by the 2024 H–2A Final Rule in 20 CFR 655.135(h)(2) and 29 CFR 501.4(a)(2) were significantly different from the previous regulatory scheme. Specifically, these protections were limited to workers who were engaged in agriculture as defined by 29 U.S.C. 203(f) of the Fair Labor Standards Act (FLSA), because these workers were exempt from the protections of the National Labor Relations Act (NLRA), 29 U.S.C. 151 *et seq.* These new protected activities were directly related to rights applicable to non-exempt workers under the NLRA, specifically: (1) engaging in activities related to self-organization, including any effort to form, join, or assist a labor organization; engaging in other concerted activities for the purpose of mutual aid or protection relating to wages or working conditions; or refusing to engage in any or all of such activities; and (2) refusing to attend an employer-sponsored meeting with the employer or its agent, representative or designee, the primary purpose of which is to communicate the employer’s opinion concerning any activity protected by this subpart; or listen to speech or view communications, the primary purpose of which is to communicate the employer’s opinion concerning any activity protected by this subpart. The new protection at § 655.135(m), introduced by the 2024 H–2A Final Rule, similarly applied only to those workers who were exempt from the NLRA, but afforded protections similar to those afforded by the NLRA. The 2024 H–2A Final Rule reasoned that these new protections, which were modeled on certain protections in the NLRA, were not preempted by the NLRA, as they applied only to those agricultural workers that are excluded from the NLRA. *See* 89 FR at 33963.

However, at this point, multiple courts have found the “worker voice and empowerment” provisions unlawful. Specifically, in *Kansas*, the U.S. District Court for the Southern District of Georgia preliminarily enjoined the Department from enforcing the 2024 H–2A Final Rule in multiple states and against certain entities and members of certain associations, finding that the worker voice and empowerment provisions of the 2024 H–2A Final Rule violated the NLRA, and thus were not

in accordance with law, because they created “collective bargaining rights” for workers whom Congress intended to exclude from the NLRA. The *Kansas* court issued a preliminary injunction specifically prohibiting the Department from enforcing the 2024 H–2A Final Rule in the states of Georgia, Kansas, South Carolina, Arkansas, Florida, Idaho, Indiana, Iowa, Louisiana, Missouri, Montana, Nebraska, North Dakota, Oklahoma, Tennessee, Texas, and Virginia, and against an individual employer and the members of a growers association as of August 26, 2024. Later, the District Court for the Eastern District of Kentucky agreed with this reasoning in *Barton*, and preliminarily enjoined certain portions of the Final Rule in Alabama, Kentucky, Ohio, and West Virginia, and with respect to a group of individuals and associations. On the same day, the United States District Court for the Southern District of Mississippi ruled in *IFPA* that the Department had exceeded its statutory authority in promulgating the regulations—specifically those related to worker voice and empowerment. The court issued a Section 705 stay of the effective date of 20 CFR 655.135(h)(2) and (m) in the 2024 H–2A Final Rule nationwide until the conclusion of proceedings in the case, including any appellate proceedings. By contrast, *NCFBF* concluded that the H–2A Final Rule was a lawful exercise of the Department’s authority under the INA.¹⁶

The 2024 H–2A Final Rule also expanded the prohibition of unfair treatment requirements at § 655.135(h) to include as protected activity consultation with “key service providers.” The 2024 H–2A Final Rule also added a definition of that term at § 655.103(b). The present definition includes the following: a health-care provider; a community health worker; an education provider; a translator or interpreter; an attorney, legal advocate, or other legal service provider; a government official, including a consular representative; a member of the clergy; an emergency services provider; a law enforcement officer; and any other provider of similar services.

This provision was intended to apply broadly, and not only to those workers engaged in agriculture under the FLSA. As this provision is not directly related to self-organization and collective action, it is not implicated by court decisions weighing the effect of the NLRA, and was not addressed in the decisions cited above, unlike the provisions in § 655.135(h)(2). The Department believes the definition of

¹⁶ *NCFBF*, 2025 WL 1296245.

“key service provider” within this provision is vague and overly broad and the lack of constraining or limiting language within this definition impermissibly expands the universe of protected activity a person can engage in. Specifically, at § 655.135(h)(1)(v), the provision states that an employer violates the law where there is any “unfair treatment” against any person who has “[c]onsulted with a key service provider on matters related to 8 U.S.C. 1188 or this subpart or any Department regulation in this chapter or 29 CFR part 501 promulgated under 8 U.S.C. 1188.” The provisions then define “key service provider” at § 655.103(b) as “A health-care provider; a community health worker; an education provider; a translator or interpreter; an attorney, legal advocate or other legal service provider; a government official, including a consular representative; a member of the clergy; an emergency services provider; a law enforcement officer; and any other provider of similar services.” The lack of constraining or limiting language in the definition of “key service provider,” most notably with the inclusion of “any other provider of similar services,” is concerning because it impermissibly expands the universe of potential protected activity in which a person can engage in. It further creates a regulatory environment in which an employer has no reasonable understanding of when a person is engaging in protected activity. The Department proposes to rescind this provision. The Department also seeks comment on whether consultation with any of the categories of persons identified in the definition of key service providers should be retained as a protected activity under 20 CFR 655.135(h) and 29 CFR 501.4(a).

The Department also proposes to rescind the regulations at 20 CFR 655.135(h)(1)(vii) and 29 CFR 501.4(a)(1)(vii) prohibiting discrimination against workers who have “[f]iled a complaint, instituted, or caused to be instituted any proceeding, or testified, assisted, or participated (or is about to testify, assist or participate) in any investigation, proceeding or hearing under or related to any applicable Federal, State, or local laws or regulations, including safety and health, employment, and labor laws.” The Department believes that this provision is duplicative of other rights under the H–2A regulations and other Federal, State, and local laws. The Department seeks comment on this proposal, including on whether this provision should be retained for the purpose of clarity.

In light of these decisions, and upon further consideration, the Department has determined that 20 CFR 655.135(h), 655.135(m), and 29 CFR 501.4, as amended by the 2024 Final Rule, may not be authorized by the INA and/or may be inconsistent with the NRLA. The Department further believes granting H–2A workers these worker-empowerment rights is not necessary to ensure that U.S. workers are not adversely affected by H–2A workers, especially given that U.S. workers do not enjoy the same worker-empowerment rights. The Department thus proposes to remove the edits made by the 2024 H–2A Final Rule and revert to the regulations in effect as of June 27, 2024. The Department similarly proposes to rescind the definitions of “key service provider” and “labor organization” added by the 2024 H–2A Final Rule at § 655.103(b). The Department invites comment on all aspects of this proposal, including any alternatives.

B. Access to Worker Housing

The Department proposes to rescind current 20 CFR 655.135(n) relating to guest access to worker housing that was added by the 2024 H–2A Final Rule. This provision requires employers to allow workers residing in employer-furnished housing to invite, or accept at their discretion, guests to their living quarters and/or the common areas or outdoor spaces near such housing during time that is outside of the workers’ workday subject only to certain limited restrictions. The 2024 H–2A Final Rule reasoned that these new provisions were needed to protect workers’ fundamental First Amendment rights of association and access to information and to prevent adverse effect on the working conditions of workers in the United States similarly employed. To support its reasoning, the Department argued that the isolation of H–2A workers, when combined with these workers’ unique vulnerabilities, renders them particularly at risk of being subject to workplace abuses, labor exploitation, and trafficking. The Department noted that the Supreme Court’s decision in *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2066 (2021), did not specifically address the type of provision at issue in § 655.135(n). 89 FR 34021 (citing authorities).

In its decision issuing a preliminary injunction in the *Barton* case, however, the United States District Court for the Eastern District of Kentucky deemed this provision an infringement on the property rights of employers amounting to a taking of the employers’ property.

757 F. Supp. 3d at 789–90 (citing *Cedar Point*, 141 S. Ct. at 2075).

The Department believes that employers’ property rights must be weighed appropriately with agricultural workers’ associational rights. Agricultural workers in the United States, including H–2A workers and workers in corresponding employment, enjoy the rights of association and to receive information from those who wish to provide it.¹⁷ Yet, as the *Barton* court reasoned, the 2024 housing access provision presents effectively imposes a government-mandated right of access to employer-furnished housing by third parties who are invited by an H–2 worker, without the property owners’ consent and regardless of the reason for entry. Such a broad right of access appears to be inconsistent with *Cedar Point*, which struck down a California regulation that was arguably narrower, as it granted access only to a specific type of person for a specific purpose and with specific time limitations. Even the NRLA grants “access to union organizers only when ‘needed,’” meaning there is “no other reasonable means of communicating with the employees.” *Cedar Point*, 141 S. Ct. at 2080–81 (Kavanaugh, J. concurring), cited at 89 FR 34021. The unqualified access granted under the 2024 housing access provision appear to be broader than “needed” and in any event may also lack statutory authority. The

¹⁷ See *Rivero v. Montgomery Cty.*, 259 F. Supp. 3d 334, 355 (D. Md. 2017) (explaining that H–2A workers, who are lawful residents of the United States, “are entitled to unfettered exchange of information just as much as any other individual in a community,” and do not “forfeit their constitutional rights by living on their employer’s premises”); see also, e.g., *Petersen v. Talisman Sugar Corp.*, 478 F.2d 73, 82–83 (5th Cir. 1973) (holding that property owner that housed migrant farmworkers on its property “must accommodate its property rights to the extent necessary to allow the free flow of ideas and information” between the migrant farmworkers and the labor and faith-based organizers that wished to visit them); *Mid-Hudson Legal Servs., Inc. v. G & U, Inc.*, 437 F. Supp. 60, 62 (S.D.N.Y. 1977) (legal service providers had First Amendment right to enter migrant community on farm property at reasonable times for the purpose of discussing with its inhabitants the living or working conditions prevalent at the farm); *Folgueras v. Hassle*, 331 F. Supp. 615, 623 (W.D. Mich. 1971) (explaining that property owner who opened up portions of his property as the living areas for those working on his farm does not have the right to censor the associations, information, and friendships of the migrants living in his camps); see also *Rivero*, 259 F. Supp. 3d at 345–48 (discussing the right of service providers and other visitors “to impart information and opinions” to these workers in their homes); *Martin v. City of Struthers*, 319 U.S. 141, 141 (1943) (“For centuries it has been a common practice in this and other countries for persons not specifically invited to go from home to home and knock on doors or ring doorbells to communicate ideas to the occupants or to invite them to political, religious, or other kinds of public meetings.”).

Department invites comment on the proposed rescission of current § 655.135(n), and specifically invites any proposed alternative provisions that may effectively balance the private property rights of employers with the free speech and association rights of workers. Additionally, the Department proposes to rescind a related provision at § 655.132(e)(1) that requires H-2ALCs using housing provided by fixed-site agricultural businesses to provide proof that such fixed-site agricultural businesses have agreed to comply with the requirements at § 655.135(n). This rescission would leave intact the other requirement of § 655.132(e)(1) that was in place prior to the publication of the 2024 H-2A Final Rule relating to the submission of proof that such housing complies with applicable health and safety standards.

C. Rates of Pay and Adverse Effect Wage Rate (AEWR) Effective Dates

The Department proposes to rescind the regulations, added by the 2024 H-2A Final Rule, expressly requiring that where there is an applicable prevailing piece rate, or where an employer intends to pay a piece rate or other non-hourly wage rate, the employer must include the non-hourly wage rate on the job order along with the highest hourly rate, and must pay workers' wages using the wage rate that will result in the highest wages for each worker in each pay period. The Department proposes to revert to the regulations in effect on June 27, 2024. These changes affected §§ 655.120(a), 655.122(l), 655.210(g), 655.211, and 653.501(c).

Both the prior and current versions of § 655.120(a) require an H-2A employer, in order to comply with its obligation under § 655.122(l), to "offer, advertise in its recruitment, and pay" a wage that is at least the highest of several enumerated wage rates, including the AEWR and any applicable prevailing wage rate. As set forth in the 2024 H-2A Final Rule, where there is an applicable prevailing piece rate, it is usually not possible to determine until the time work is performed whether the prevailing piece rate will be higher than the highest of the applicable hourly wage rates as this will depend on worker productivity.¹⁸ This led to conflicting interpretations of the requirements at §§ 655.120(a) and 655.122(l). The Department's Board of Alien Labor Certification Appeals (BALCA), construing earlier versions of the regulations, concluded that OFLC can only require H-2A employers to list a wage that is at least equal to the

highest applicable hourly wage rate—usually the AEWR—on job orders because OFLC does not know at the certification stage whether the prevailing piece rate will be higher than the hourly wage. 89 FR 33957 (citing *Golden Harvest Farm*, 2011-TLC-00442, at *3 (BALCA Aug. 17, 2011); *Dellamano & Assocs.*, 2010-TLC-00028, at *5-7 (BALCA May 21, 2010); and *Twin Star Farm*, 2009-TLC-00051, at *4-5 (BALCA May 28, 2009)). Based on these decisions, OFLC did not require employers to list applicable prevailing piece rates on job orders and, in most instances, WHD could not enforce those prevailing piece rates even when these would have resulted in higher earnings for workers. 89 FR 33957. In contrast, the Ninth Circuit, in adjudicating a challenge to OFLC's practice of not requiring that applicable prevailing piece rates be included on job orders, held that the prior version of § 655.120(a) requires that applicable prevailing piece rates be included on job orders because a piece rate wage offers workers "the opportunity to earn more than they might under an hourly wage." *Torres Hernandez v. Su*, 2024 WL 2559562, at *1 (9th Cir. 2024). The Ninth Circuit stated that "allowing employers and DOL to ignore piece-rate prevailing wages under § 655.120(a) would largely nullify § 655.120(c), which defines the procedure for determining prevailing wages." *Id.* ("There is no reason to think that the regulations contemplate calculating piece-rate prevailing wages under § 655.120(c) but exclude such wages from consideration under § 655.120(a).").

Anticipating the Ninth Circuit's decision in *Torres Hernandez*, DOL revised the applicable regulations. The 2024 H-2A Final Rule revised §§ 655.120(a) and 655.122(l) to expressly require that, where there is an applicable prevailing piece rate, or where an employer intends to pay a piece rate or other non-hourly wage rate, the employer must include the non-hourly wage rate on the job order along with the highest hourly rate, and to clarify that, in such instances, an employer must pay workers' wages using the wage rate that will result in the highest wages for each worker in each pay period. The Department made analogous changes to the regulations at §§ 655.210(g) and 655.211, which govern rates of pay for herding and range livestock occupations, as well as corresponding changes to § 653.501(c)(1)(iv)(E).

However, whether an employer is obligated to disclose a piece rate or other non-hourly rate in the job offer

and whether that piece rate or other non-hourly rate, once disclosed, must be paid if it results in higher wages than the AEWR, remains contested and is actively being litigated. Following the Department's issuance of the 2024 H-2A Final Rule, the United States District Court for the Eastern District of Kentucky enjoined the Department from enforcing the "new minimum pay requirements including but not limited to §§ 655.120(a) and 655.122(l)" with respect to employers belonging to plaintiff agricultural associations, among others. *Barton*, 757 F. Supp. 3d at 794. Consistent with this injunction, the Department ceased requiring affected employers to list applicable prevailing piece rates on their job orders, only for a new claim to be filed against it challenging the cessation. Applying the Ninth Circuit's rationale, the United States District Court for the Western District of Washington ordered the Department to resume requiring employers to offer and pay applicable prevailing piece rates for work in Washington State. *Familias Unidas Por La Justicia v. DOL*, No. 24-cv-00637 (W.D. Wash. Mar. 28, 2025, modified Apr. 24, 2025). To ensure its compliance with both injunctions, the Department is now administering and enforcing the requirements of §§ 655.120(a) and 655.122(l) differently in different jurisdictions, resulting in two distinct regulatory schemes. Employers seeking to hire H-2A workers in most parts of the country are not required to include applicable prevailing piece rates on job orders consistent with the *Barton* order. However, that order does not affect the versions of §§ 655.120(a) and 655.122(l) that were in place prior to the 2024 H-2A Final Rule. Consistent with the Ninth Circuit's interpretation of the pre-2024 regulations in *Torres Hernandez* and with the *Familias* injunction, for work to be performed in Washington State, employers must offer and pay any applicable prevailing piece rates.

In light of this ongoing litigation and the resulting differences in enforcement nationwide, the Department proposes to rescind current § 655.120(a)(1)(vi) and (a)(2) and revert to the version of § 655.120(a) in effect as of June 27, 2024. Similarly, the Department proposes to rescind current § 655.122(l) and replace it with the version of § 655.122(l) in effect as of June 27, 2024. The reasons for rescinding §§ 655.122(l)(3) and (4), relating to productivity standards and overtime disclosure, are discussed later in this NPRM. For the same reasons, the Department proposes to rescind current § 655.210(g) and § 655.211 and replace these provisions with the versions of

¹⁸ 89 FR at 33956-57.

§ 655.210(g) and § 655.211 in effect as of June 27, 2024. The Department also proposes to rescind the current § 653.501(c)(1)(iv)(E) and replace it with the version of § 653.501(c)(1)(iv)(E) in effect as of June 27, 2024 because these corresponding changes were made in the interest of having analogous processes and requirements, where possible, for the review of H-2A (criteria) and non-H-2A (non-criteria) clearance orders.

The Department notes that, given the *Familias* injunction, as well as the Ninth Circuit's decision in *Torres Hernandez*, both of which apply to the pre-2024 version of these provisions, the intended effect of the proposed rescission will be to clarify that employers seeking to employ H-2A workers outside of the Ninth Circuit are not required by § 655.120(a) to list applicable prevailing piece rates on job orders.

The Department requests comments on all aspects of this proposal. Specifically, the Department solicits comments from employers who pay piece rates on how and why they choose to pay piece rates, whether they use piece rates in recruiting, and how they track time and productivity on different crops. The Department also solicits comments from employees and advocates on how frequently workers are paid piece rates, and how workers will know that a piece rate will be offered on a job if these provisions are rescinded, and generally the impact of the disclosure on the job order of the availability of a piece rate. Finally, the Department solicits comments on how this proposal interacts with the Department's statutory mandate to prevent adverse effect on similarly employed workers in the United States, and that employers hire H-2A workers only when there are not sufficient workers who are able, willing, qualified, and available to perform the work.

The Department also proposes to rescind the 2024 H-2A Final Rule provisions at § 655.120(b)(2)–(3), which currently designate the effective date of each updated AEW as the date of publication in the **Federal Register** and require employers to pay the updated AEW immediately upon publication of the new AEW in the **Federal Register**. Instead, the Department proposes to revert to the regulations that were in effect on June 27, 2024.

The Department reasoned in the 2024 H-2A Final Rule that such a change was necessary in order to ensure H-2A and corresponding workers receive the most current AEW at the time work is performed, but in doing so it departed from a practice of providing a

reasonable adjustment period for employers after publication of updated AEWs. The Department has long required employers participating in the H-2A program to offer and pay the highest of the AEW, the prevailing wage, any agreed-upon collective bargaining wage, or the Federal or State minimum wage at the time the work is performed, upon the effective date stated in the notice of new AEWs in the **Federal Register**.¹⁹ The 2024 H-2A Final Rule provision at § 655.120(b)(2) constituted “a departure from more recent practice . . . which allowed a minor period for wage adjustment after publication of the FRN.”²⁰ Prior to the 2024 H-2A Final Rule, the Department “identifie[d] the effective date of the new AEWs” in “the **Federal Register** notice publishing the updated AEWs . . .” and the Department’s uncodified practice “provid[ed] employers a short period of time (*i.e.*, up to 14 days) to update their payroll systems, such that an employer would not be required to adjust a worker’s pay in the middle of a pay period, but would be required to promptly implement the adjustment.”²¹

The Department has reconsidered the decision to deviate from practice and, similar to the Department’s conclusion in the 2022 H-2A Final Rule, the Department has concluded that reinstating the prior practice of providing an AEW effective date in FRNs that provide a period of up to 14 days for employers to identify AEW changes and adjust payroll most effectively balances the need to ensure H-2A and U.S. workers receive timely payment of wages necessary to prevent adverse effect with the need to provide employers adequate time to adjust to new AEWs after the Department publishes notice.²² The Department

proposes to continue to require employers to contractually agree to pay updated wages to H-2A foreign workers and corresponding workers and to make mid-contract updates to the AEWs upon the effective date stated in the Department’s FRNs, but proposes to revert to the policy of setting the effective date of the updated AEW on a date up to 14 days after publication of the FRN. The Department believes this reinstatement of prior policy, which it previously acknowledged “may alter employer budgets for the season,”²³ would best balance the Department’s statutory mandate to ensure the employment of H-2A foreign workers does not adversely affect the wages of workers in the United States similarly employed with the need for sound administration of the H-2A program, by providing a reasonable adjustment period for employers to receive notice of, and make changes to accommodate, updated AEWs without imposing unnecessary regulatory burdens that may unreasonably subject employers to investigation and enforcement actions.

The Department recognizes that this issue has been the subject of contention and concern, particularly regarding the burden that this requirement would have on employers, including reasonable concerns that employers cannot immediately update payroll or pay structures, and especially cannot do so when they are required to monitor the **Federal Register** for the Department’s notices, and must conduct operational planning, and that a limited adjustment period is necessary to ensure employers receive notice of the new AEW obligation and to make payroll adjustments that in some cases may be difficult and require a brief period of time to complete. The need for a brief adjustment period is especially pertinent for employers who may be subject to multiple AEWs—a Farm Labor Survey (FLS)-based AEW and occupation-specific AEW based on the Occupational Employment and Wage Statistics (OEWS) survey—under the 2023 H-2A AEW Final Rule,²⁴ either one of which may be applicable upon publication of updated AEWs, depending on which is highest. The 2024 H-2A Final Rule deviation from prior policy also failed to adequately account for the fact that FRN publication dates can be unpredictable, given the Department does not control the dates it receives the underlying FLS or OEWS data on which AEWs are

¹⁹ See, e.g., 1987 H-2A IFR, 52 FR 20496, 20521; Labor Certification Process for the Temporary Employment of Aliens in Agriculture in the United States; H-2A Program Handbook, 53 FR 22076, 22095 (Jun. 13, 1988) (“Certified H-2A employers must agree, as a condition for receiving certification, to pay a higher AEW than the one in effect at the time an application is submitted in the event publication of the [higher] AEW coincides with the period of employment.”)

²⁰ 89 FR at 33955.

²¹ 87 FR at 61688 (citing *Notice, Labor Certification Process for the Temporary Employment of Aliens in Agriculture in the United States: 2020 Adverse Effect Wage Rates for Non-Range Occupations*, 84 FR 69774 (Dec. 19, 2019) (announcing AEWs for 2020 on December 19, 2019, to be effective January 2, 2020)).

²² See *id.* (declining to “require immediate implementation” of AEWs or codify an AEW effective date, instead maintaining “current practice of stating the effective date of the new AEWs in the **Federal Register** announcement of the new AEWs, which may be immediate and will not be more than 14 calendar days after publication of that notice, consistent with historical and current practice.”).

²³ See 75 FR at 6901; 87 FR at 61688.

²⁴ 88 FR 12760 (Feb. 28, 2023).

based,²⁵ and a reasonable adjustment period provides flexibility to employers to cushion against this predictability. The Department believes reinstating the prior policy of providing a brief adjustment period would most effectively balance the need to provide reasonable flexibility to employers with the need to ensure the wages of workers in the United States similarly employed are not affected.

Therefore, the Department proposes to rescind current § 655.120(b)(2)–(3) and reinstate the § 655.120(b)(2)–(3) AEWR requirements in effect prior to the 2024 H–2A Final Rule. Under this proposal, the Department would revert to the practice that was in place, prior to the 2024 H–2A Final Rule, which allowed a minor period for wage adjustment after publication of the FRN. Under this practice, when publishing the **Federal Register** notice containing updated AEWRs, the Department would state the effective date of the new AEWRs in the notice and generally set the effective date of the new AEWRs at no later than 14 calendar days from the publication of that notice.

D. Enhanced Information Collection Requirements

The Department proposes to rescind the additional information disclosure requirements at § 655.130(a)(1)–(4) in the 2024 H–2A Final Rule, which required the employer provide, at the time of filing, the identity, location, and contact information for the owner(s) of each employer, any person or entity who operates a place of employment, and any person who manages or supervises workers employed under the H–2A Application. Additionally, the rule required employers to provide their prior trade/DBA names used in the most recent 3-year period preceding its filing of the H–2A Application. Consistent with these revisions, a new § 655.167(c)(9) included a recordkeeping provision requiring the employer to keep this information up-to-date until the end of the work contract period and retain the information for three years.

The Department anticipated that these revisions would allow the Department to gain a more accurate and detailed understanding of the scope and structure of the employer's agricultural operation and thereby assist the Department in program administration

and enforcement, including in determinations of whether an employer has demonstrated a bona fide temporary or seasonal need, or, conversely, whether an employer has, through multiple related entities, sought to obtain year-round H–2A labor. The Department further reasoned that collecting this additional information would enhance the Department's enforcement capabilities by helping the Department identify, investigate, and pursue remedies from program violators and ensure that sanctions, such as debarment or civil money penalties, are appropriately assessed.

The Department has determined collection of owner, operator, manager, and supervisor information at the time of application filing presents legal risks and places extensive burdens on filers while providing limited utility in the stated goals, such as single employer test determinations.

While the collection of the information may result in identifying program violations and allow the Department to seek appropriate sanctions where violations occur, the Department need not collect this information at the time of filing, as it can seek this information when necessary to demonstrate program compliance at the time of an audit or investigation and enforcement action. The Department did not appropriately balance the likelihood of uncovering important information, such as program violations, against the burden on employers of providing such information to the Department at the time of filing. The benefit to the Department is minimal when compared to the burden placed on law-abiding employers to provide this information in every case, and the Department believes the practical utility of collecting the information at the time of filing is significantly outweighed by the burden on the public. The Department has concluded that the more practical approach is to continue to collect pertinent information such as information about owners and operators of worksites when it is necessary for enforcement or investigatory purposes. Therefore, the Department proposes rescinding the enhanced information collection provisions in the 2024 H–2A rule to permit the Department to instead collect such information in other ways as it did prior to the 2024 H–2A Final Rule, as needed, such as from the subject of an investigation rather than from all employers of H–2A workers.²⁶

Therefore, the Department proposes to rescind the current § 655.130(a)(1)–(4)

and reinstate the § 655.130(a) filing requirements in effect prior to the 2024 H–2A Final Rule. Under this proposal, the Department would again require only that the employer disclose information about the identity of the employer and its agent or attorney; the places where work will be performed; and, when requested by the Certifying Officer (CO), the employer's use of a foreign labor recruiter, and provide any necessary supporting documentation required at the time of filing under §§ 655.131 through §§ 655.135. Consistent with this proposal, the Department also proposes to rescind § 655.167(c)(9) governing document retention related to the § 655.130(a) requirements.

E. Seat Belts

The Department proposes to rescind the requirement, added by the 2024 H–2A Final Rule, to require the provision, maintenance, and wearing of seat belts in most employer-provided transportation. The 2024 H–2A Final Rule revised 29 CFR 655.122(h)(4) to prohibit an employer from operating any employer-provided transportation unless all passengers and the driver were properly restrained by seat belts meeting standards established by the U.S. Department of Transportation (U.S. DOT), as long as the transportation was manufactured with seat belts pursuant to U.S. DOT's Federal Motor Vehicle Safety Standards. The Department proposes to return to the language of § 655.122(h)(4) in effect as of June 27, 2024, which prior to the effective date of the 2024 H–2A Final Rule, made no mention of seat belts but required that all employer-provided transportation comply with all applicable local, State, or Federal laws and regulations and provide, at a minimum, the same transportation safety standards, driver licensure, and vehicle insurance as required under 29 U.S.C. 1841, 29 CFR 500.104 or 500.105, and 29 CFR 500.120 through 500.128, and outlined other requirements for disclosure of transportation modes and use of workers' compensation for vehicle transportation purposes. In other words, the Department proposes to rescind current § 655.122(h)(4)(ii), but retain and recombine into a single paragraph § 655.122(h)(4) current § 655.122(h)(4)(i), § 655.122(h)(4)(iii), and § 655.122(h)(4)(iv).

The 2024 H–2A Final Rule reasoned that the provision of seat belts in employer-provided transportation, and the requirement that employers ensure that workers wear seat belts, was necessary to prevent adverse effect on the wages and working conditions of

²⁵ See 89 FR at 33956 (noting the Department “does not control the publication dates of BLS and USDA data” and “it is administratively impractical for the Department to publish AEWRs on the same date that BLS and USDA publishes the underlying data” and “given the resources required to draft an FRN”).

²⁶ See 5 U.S.C. 552a(e)(2).

similarly employed workers in the United States because H-2A workers may have more limited recourse than workers in the United States similarly employed when placed in an inherently dangerous situation, such as being transported in a vehicle without seat belts. Additionally, the NPRM reasoned that unbelted passengers posed a grave safety risk to other passengers, including non-H-2A workers, in the event of a crash.²⁷

The *Barton* court found the 2024 H-2A Final Rule's provision requiring the wearing of seat belts to be arbitrary and capricious because the Department did not explain how holding employers liable for an employee's failure to wear a seat belt would avoid downgrading worker safety conditions. *Barton*, 757 F. Supp. 3d at 788–89. Instead, the court reasoned, the requirement would degrade working conditions because employees would find themselves under greater levels of scrutiny and supervision. *Id.* The court further reasoned that the requirement holds H-2A employers to a higher standard than that to which other agricultural employers are subject, and noted that employers have little control over whether their employees choose to wear seat belts. *Id.* The court did not specifically address the 2024 H-2A Final Rule's requirement that employers provide and maintain seat belts in most employer-provided transportation, *id.*, yet still enjoined this portion of the rule.

Upon further review, and in light of the court's decision in *Barton*, the Department no longer believes that these requirements serve the statutory purpose of preventing adverse effect on similarly employed workers in the United States. The transportation safety requirements under the Migrant and Seasonal Agricultural Worker Protection Act, 29 U.S.C. 1801 *et seq.* and 29 CFR part 500 Subpart D, which cover many of the agricultural workers in the United States without H-2A visas, do not specifically require the provision of seat belts nor that employers ensure that workers are wearing seat belts. The current § 655.122(h)(4)(ii), therefore, requires more heightened safety measures for employers employing H-2A workers than those employing only U.S. workers, which does not meaningfully achieve the statutory goal of protecting similarly employed workers from adverse effect from the employment of foreign workers.

This proposed rescission does not affect the Department's perspective on the safety benefits of seat belts. Seat belts continue to be one of the most

effective ways to prevent serious injuries and fatalities in vehicle crashes. The Department reminds employers using the H-2A program that they must continue to comply with all applicable local, State, and Federal laws relating to transportation safety, including those relating to seat belts.

The Department invites comment on the rescission of current § 655.122(h)(4)(ii). Specifically, the Department seeks comment on the potential effect this proposal may have on similarly employed workers in the United States, the importance of and/or burden posed by current § 655.122(h)(4)(ii), and whether any part of this provision should be retained (*e.g.*, retaining the requirement that employers provide and maintain seat belts if the vehicle was manufactured with seat belts but not the requirement that employers require their workers to wear seat belts).

F. Termination for Cause

The Department proposes to rescind regulations defining termination for cause, establishing five conditions that must be satisfied before an employer may terminate a worker for cause, and setting recordkeeping requirements associated with termination for cause, including requirements for maintaining disciplinary records and termination records. Specifically, the Department proposes to return to the regulatory language of 20 CFR 655.122(n) as of June 27, 2024, prior to the 2024 H-2A Final Rule, which only stated that an employer was relieved of certain obligations if a worker was terminated for cause or abandoned work, and then only if timely required notification of government agencies was made, and established basic recordkeeping requirements related to this notification. In other words, the Department proposes to rescind current 20 CFR 655.122(n)(2), (n)(4)(ii) and (n)(4)(iii) and recombine the remaining language in one paragraph. The Department also proposes to rescind corresponding recordkeeping requirements at § 655.167(c)(10) and (11).

In the 2024 H-2A Final Rule, the Department defined termination for cause and outlined five conditions that must be met before a termination for cause could occur, one of which was that the employer must first correct the worker's performance or behavior using progressive discipline. The 2024 H-2A Final Rule further clarified what situations will never constitute termination for cause. The Department reasoned that these changes were necessary to promote the integrity and regularity of any such processes and to

help ensure that employers do not arbitrarily and unjustly terminate workers, thereby stripping them of essential rights under the H-2A program which serve to protect similarly employed workers against any potential adverse effect from the employment of H-2A workers (namely the right to outbound transportation and subsistence, the three-fourths guarantee, and, in the case of U.S. workers, the right to be contacted in subsequent years).

Upon further review, the Department believes that these regulations are overly burdensome and unnecessary. For decades, the Department has enforced the requirement that a worker is owed outbound transportation and subsistence, the three-fourths guarantee, and, if the worker is a U.S. worker, the right to be contacted for employment the subsequent year, unless he or she is terminated for cause or abandons employment. Only in 2024 did the Department determine that it needed a rigid set of criteria and recordkeeping before it would accept any termination as being “for cause.” Indeed, the Department acknowledged in the 2024 H-2A Final Rule that “[h]istorically, when determining whether a worker has been terminated for cause, the Department has reviewed all relevant factors, including, for example, the reasonableness of the rule, consistent application of a rule among employees, and whether the employer fairly reviewed the misconduct or job performance.”²⁸ Upon further review, the Department believes that previous procedures were sufficient to identify when a worker was terminated for cause and seeks to remove the complicated, burdensome, and overly prescriptive framework in 20 CFR 655.122(n)(2) from the regulations.

Furthermore, certain provisions in current § 655.122(n)(2) have become untethered from the statutory mandate of protecting similarly employed workers in the United States from adverse effect from the employment of foreign workers. Specifically, the requirement that an employer progressively discipline a worker before terminating that worker for cause has no meaningful connection to preventing the employment of H-2A workers from adversely affecting the wages and working conditions of similarly employed workers in the United States. Most workers in the United States are not entitled to progressive discipline (although progressive discipline, or lack thereof, may be instructive in determining whether a reason for

²⁷ See 89 FR at 33963.

²⁸ 89 FR at 33970.

termination is pretextual). The Department believes that explicitly requiring an employer using the H-2A program to progressively discipline a worker before terminating them for cause does not meaningfully protect similarly employed workers in the United States; there may be many situations where termination for cause is appropriate even without progressive discipline, and other situations where termination for cause is not appropriate even if the employer has gone through a progressive discipline process. The 2024 H-2A final rule developed a system where any termination for cause required progressive discipline, which is not reflective of the working world for most people in the United States, where progressive discipline is generally not explicitly required by law to effectuate a termination for cause. While the Department continues to emphasize the importance of safeguarding essential and longstanding worker protections in the H-2A program (specifically, the right to outbound transportation and subsistence, the three-fourths guarantee, and, if the worker is a U.S. worker, the right to be contacted for subsequent employment), it no longer believes that explicitly requiring progressive discipline before an employer terminates a worker for cause achieves that goal.

The Department solicits comments on this proposed rescission. Specifically, the Department solicits comments as to potential effect this proposal may have on similarly employed workers in the United States, the importance of and/or burden posed by current § 655.122(n)(2), and whether any part of this provision should be retained either in regulation or in subregulatory guidance (e.g., retain the definition of termination for cause in § 655.122(n)(2) but remove the five criteria, or retain § 655.122(n)(2)(i)(A)–(D) in subregulatory guidance).

The Department also proposes to rescind current 20 CFR 655.122(l)(3) and reinstate the 20 CFR 655.122(l)(2)(iii) in effect as of June 27, 2024, prior to the 2024 H-2A Final Rule. In order to align the regulations with changes to § 655.122(n)(2), the 2024 H-2A Final Rule required that all employers requiring one or more productivity standards as a condition of job retention disclose those standards in the job order, and set a ceiling on the productivity standards. Prior to the 2024 H-2A Final Rule, § 655.122(l)(2)(iii) only required disclosure and the ceiling if the employer paid by a piece rate and required the productivity standard as a condition of job retention. As the Department proposes to rescind the regulation that necessitated this change

(current § 655.122(n)(2)), it similarly proposes to revert to the regulatory text of § 655.122(l)(2)(iii) before the effective date of the 2024 H-2A Final Rule. The Department solicits comments on this proposal, including on whether an employer who has productivity standards as a condition of job retention but does not pay by a piece rate should be required to disclose the productivity standards in the job order.

G. Disclosure of Foreign Labor Recruiter Information

The Department proposes to rescind all regulatory and related data collection requirements requiring employers to identify any foreign labor recruiters, and to provide copies of the agreements between the employer and such recruiter(s) at the time of filing. Specifically, the Department proposes to rescind § 655.137, *Disclosure of Foreign Worker Recruitment*, a related assurance at § 655.135(p), and § 655.167(c)(8) that provides applicable document retention requirements.

The regulatory requirements at § 655.137 govern what information and documentation an employer must provide at filing regarding foreign worker recruitment, as well as how it must maintain and update that information. These provisions also address the Department's dissemination or publication of the information it receives. Paragraph (a) requires that if the employer engaged or plans to engage an agent or foreign labor recruiter, directly or indirectly, in international recruitment, the employer, and its attorney or agent, as applicable, must provide copies of all contracts and agreements with any agent or recruiter or both, executed in connection with the job opportunity, a requirement that is also covered by the assurance at § 655.135(p). These agreements must contain the contractual prohibition against charging fees as set forth in § 655.135(k). In paragraph (b), the Department requires that applications must contain all recruitment-related information required in the *Application for Temporary Employment Certification*, as defined in § 655.103(b), including the identity and location of all persons and entities hired by or working for the recruiter or agent, and any of the agents or employees of those persons and entities, to recruit prospective foreign workers for the H-2A job opportunity. Paragraph (c) of § 655.137 requires that employers must continue to keep the foreign labor recruiter information referenced in paragraphs (a) and (b) up to date until the end of the work contract period, with this updated information available in the event of a

post-certification audit or upon request by the Department.

The Department is also proposing to rescind § 655.167(c)(8) governing applicable employer document retention requirements. Finally, the Department proposes to rescind paragraph (d) of § 655.137, which required the Department to maintain a publicly available list of agents and recruiters (including government registration numbers, if any) who are party to the agreements employers submit, as well as the persons and entities the employer identified as hired by or working for the recruiter and the locations in which they are operating.

Based on a review of the 2024 H-2A Final Rule, the Department has determined it did not adequately address the legitimate concerns raised by commenters regarding the time and burden to collect this information; the need for employers to understand their information disclosure, retention, and production obligations; the ability to access this information and the timing of the collection, including the obligation and burden to update the information. The Department also did not adequately explain why this information must be collected at the time of filing *Application for Temporary Employment Certification*, in addition to similar collections at the time the employer files a petition with the Department of Homeland Security (DHS). The Department notes that DHS has statutory authority for the admission of foreign beneficiaries under the H-2A visa classification and the United States Citizenship and Immigration Services (USCIS) requires employers to provide identifying information about agents and recruiters, including addresses, at the time of filing the H-2A petition. Specifically, the Form I-129 requires the employer to provide the names and addresses of all agents, facilitators, staff, recruiters, or any person or entity that recruits or solicits prospective beneficiaries of an H-2 petition.

The Department also overstated the value the additional disclosure of information would provide in “aiding enforcement of provisions like § 655.135(k), which prohibits seeking or receiving of recruitment fees,” as well as the value in “better . . . map[ping] international recruitment relationships” to “identify where prohibited fees are collected . . .”²⁹ The fact that there exists the current practice of collecting this information in the H-2B program does not justify its collection in the H-2A program, especially in light of the

²⁹ 89 FR at 34026.

significant reporting burden on employers.

The 2024 H–2A Final Rule requirement to disclose contracts and agreements with international recruiters and additionally provide identifying information for the recruiter’s employees and anyone within the recruitment chain engaged in foreign worker recruitment, and to maintain these records for a period of three years from certification, imposes significant burdens. The burdens include the completion of paperwork, disclosures at the time of filing, information security related to retention of identifying information, and potential breach of privacy claims, as well as imposing an unnecessarily thorough duty to inquire into every link in the international recruitment chain to ascertain the “identity and location of all persons and entities hired by or working for the recruiter or agent, and any of the agents or employees of those persons and entities . . .”³⁰ While the additional disclosures may provide H–2A foreign workers a better sense of the foreign labor recruiters used by their employers or prospective employers and “better understand[ing] [of] the roles of recruiters . . . in the recruitment chain . . .”³¹ the Department does not think the benefit outweighs the burden. Furthermore, the Department has lacks both the resources and methods to verify, at the time of filing, that the employer provided complete information about the recruiters the employer used independently verify the validity of the data the employer provides at the time of processing, so it cannot be sure that H–2A foreign workers have accurate or complete information to decide whether a recruiter is legitimate. The inability of the Department to verify the completeness or accuracy of the information, and therefore its utility to potential H–2A workers, leads the Department to conclude it cannot justify the burden placed on employers to provide this information.

Therefore, the Department proposes to eliminate §§ 655.135(p), 655.137, and 655.167(c)(8), and maintain the existing provisions like §§ 655.135(j) and (k) that provide measurable value in protecting U.S. and foreign workers through prohibitions against unlawful fees and enforcement of related contractual obligations and provide authority for WHD to enforce compliance with these provisions. The Department believes the regulations in existence prior to the 2024 H–2A Final Rule will provide

sufficient protection against exploitation and abuse of foreign workers by foreign labor recruiters and permit the Department to enforce provisions prohibiting imposition of unlawful fees in a framework that is consistent with the scope of the Department’s statutory authority. The regulations at § 655.135(j), generally prohibit the employer and its agents from seeking or receiving fees related to H–2A labor certification, including recruitment costs. The regulations at § 655.135(k) more specifically require the employer to contractually prohibit in writing any foreign labor contractor or recruiter (or any agent of such foreign labor contractor or recruiter) whom the employer engages from seeking or receiving payments or other compensation from prospective workers and to provide documentation of the prohibition upon request by the Department or a Federal party. Under these provisions, the Department may, in the course of an audit or investigation, request the employer present documentation demonstrating the contractual arrangement with a foreign labor recruiter and demonstrating compliance with the H–2A provisions and are sufficient to permit WHD to “identify individuals charging fees, connect such individuals’ relationships with recruitment agencies contracted by the employer, determine whether all entities had contractually prohibited cost-shifting as required under § 655.135(k), and hold the appropriate parties responsible,” without imposing unnecessary burdens on employers to disclose the identity of every individual within the international recruitment chain to the Department at the time of filing the *Application for Temporary Employment Certification*.³²

H. Minor Delays in Start Date of Work

The Department proposes to eliminate § 655.175, including the new delayed start date procedure and related assurances and obligations promulgated in the 2024 H–2A Final Rule. Instead, the Department proposes to revert to the regulatory scheme that governed the delayed start date process for many years prior to the 2024 H–2A Final Rule. Section 655.175, as well as a related recordkeeping obligation at § 655.167(c)(12) and conforming changes to §§ 655.122(i) and 655.145(b), were intended to clarify employer obligations in the event of a delay in the start of work and to distinguish post-certification delays from pre-certification Application amendments

under current § 655.145(b). The rule defines a “minor” delay in the start of work as a delay of 14 calendar days or fewer and continues to limit these delays to situations in which unforeseen circumstances require the delay and the employer’s crops or commodities would be in jeopardy prior the expiration of an additional, expedited recruitment period. The rule also requires the employer to contact the SWA and workers at least 10 business days prior to the start date and maintains the existing requirement that the employer provide housing and subsistence to any worker already traveling to the worksite. If the employer fails to provide this notice, the rule requires employers to provide compensation to workers for each day work is delayed during the delay period, at the highest hourly rate specified in the applicable regulations, for a period of up to 14 calendar days, and provide this compensation no later than the date workers would have been paid had work begun on time, similar to the Wagner-Peyser Act (WP Act) provision at § 653.501(c), which covers U.S. workers the SWA refers to the employer’s job opportunity. This provision also requires employers to send notice to workers of the delay using an electronic method, when possible, and translate the notice into a language workers can understand, similar to the current work contract translation language at § 655.122(q). Consistent with these changes, § 655.167(c)(12) includes a recordkeeping provision requiring the employer to maintain a record that it sent notice of the delayed start of work.

Beginning with the 2010 H–2A Final Rule, OFLC regulations have permitted an employer to request a delay in the start date after submitting a written request to the CO and receiving the CO’s approval. Section 655.145(b) in that rule explained that if the request is for a delay in the start date and is made after workers have departed for the employer’s place of work, the CO may only approve the change if the employer includes with the request a written assurance signed and dated by the employer that all workers who are already traveling to the job site will be provided housing and subsistence, without cost to the workers, until work commences. Upon acceptance of an amendment, the CO would submit to the SWA any necessary modification to the job order. This provision required the employer to show that the delay was caused by unforeseeable circumstances and demonstrate that the crops or commodities will be in jeopardy prior to the expiration of an additional

³⁰ *Id.* at 34025.

³¹ *Id.* at 34026.

³² 89 FR at 34026.

recruitment period. It also required an employer seeking a post-certification delay in the start of work to provide housing and subsistence to workers who had already begun traveling to the place of employment and comply with the WP Act regulations at § 653.501(c). Similarly, the WP Act regulations pre-dating the 2024 H-2A Final Rule “provide[] a process close to the start date the employer identified in the job order for the employer, the SWA, and referred farmworkers to communicate regarding the actual start date of work.”³³ These provisions “require[] an employer to notify the SWA of start date changes at least 10 business days before the originally anticipated start date and require the SWA to notify farmworkers that they should contact the SWA between 9 and 5 business days before the anticipated start date to verify the actual start date of work.”³⁴

The Department proposes to revert to the delayed start date provisions under the 2010 and 2022 H-2A Final Rules. Consistent with this proposal, the Department proposes to revise § 655.145(b) and, as discussed further below, 653.501(c), to mirror language in place beginning in the 2010 H-2A Final Rule. As under the 2010 and 2022 H-2A Final Rules, this proposed language requires the employer to request CO approval for a minor delay in the start date, demonstrate unforeseeable circumstances that jeopardize crops, and assure the CO that if the employer requests a start date delay after workers have departed for the place of employment, the employer will provide housing and subsistence to all workers who are already traveling to the place of employment, without cost to the workers, until work commences. If the employer fails to comply with its obligations, the Department may pursue revocation of the temporary agricultural labor certification under § 655.181 or debarment of the employer under § 655.182 or 29 CFR 501.20. The Department proposes to reinstate § 655.122(i)(1)(i) and (ii) as effective prior to the 2024 H-2A Final Rule, which reflect that the work contract period can be shortened by agreement of the parties with the approval of the CO. These provisions were removed during the prior rulemaking to ensure consistency with § 655.175(b), which permitted only minor delays to the start date of work and did not require CO approval of the delay. The Department also proposes to remove the

recordkeeping obligation at § 655.167(c)(12), as necessary for consistency with the above proposals.

These proposals are consistent with President Trump’s E.O. directing the Department to reduce regulatory complexity, reduce burdens on program users, and rescind or revise regulations that are inconsistent with the Department’s clear statutory authority. The provision at § 655.145(b) provides similar flexibility to employers as § 655.175, consistent with the Department’s acknowledgment that the actual day work begins may vary due to such factors as travel delays or crop conditions at the time the employer expects work to begin. This proposed rule maintains existing emergency filing procedures at § 655.134 to accommodate employers faced with exigent circumstances necessitating a longer delay in the start date of work. The Department has determined workers similarly employed are provided adequate protections in the event of a delayed start date through the pre-2024 WP Act provisions requiring notice of the delay by SWAs and compensation of U.S. workers under § 653.501(c), the requirement that employers guarantee H-2A and corresponding workers a total number of work hours equal to at least three-fourths of the workdays of the total period of employment under § 655.122(i), and the § 655.145(b) language limiting delayed start date requests to a minor period, justified by unforeseeable circumstances that jeopardize crops, and subject to CO approval, as well as a determination that the test of the U.S. labor market will not be impacted, and employer assurances related to provision of housing and subsistence to workers traveling to the worksite at the time of the delay. In contrast, the 2024 H-2A Final Rule provision providing additional notice and recordkeeping burdens and extending the WP Act compensation obligation to H-2A foreign workers was not necessary to prevent adverse effects on the wages and working conditions of similarly employed workers.

Additionally, the Department’s elimination of the requirement for employers to obtain CO approval of changes to start dates reduced filing burdens on employers and administrative burdens on the Department and SWAs related to adjudication of requests and notice of delay to workers, but also made it more difficult for the Department to ensure that employers provide notice of delays to workers, provide accurate start dates in filings, and delay start dates only where necessitated by exigent circumstances unforeseeable at the time

of filing and only when the Department determined the change would not impact the labor market test and the employer would comply with assurances to provide housing and subsistence to workers already en route to the worksite. The Department believes reversion to the delayed start date provisions implemented prior to the 2024 H-2A Final Rule will best balance the need for agricultural employers to respond to unforeseeable exigent circumstances and the need to ensure U.S. workers are accurately apprised of the start date of work in the event of a minor delay, and do not suffer financial hardship or material changes to terms and conditions of employment as a result of the employer’s employment of H-2A foreign workers.

I. Other Regulatory Provisions Clarifying Existing Policy or Procedural Standards

The Department proposes to retain several provisions adopted in the 2024 H-2A Final Rule that merely codified existing practice or streamlined procedures and imposed no additional burdens on employers, the Department, or U.S. or foreign workers. While the Department is proposing to retain these provisions, it seeks public comment to determine if any changes are appropriate or necessary. The Department will consider any comments on the provisions listed below when developing the Final Rule.

First, the Department proposes to retain the definition of single employer and the explanation of the single employer test at § 655.103(e) and 29 CFR 501.3(d). This provision codified the test that the Department had already implemented in practice, but had not included in its regulations prior to the 2024 H-2A Final Rule. The Department believes this provision provides clarity to filers about when and how the Department will determine that two seemingly separate entities will be evaluated to determine whether they are in fact one entity for the purpose of ensuring compliance with H-2A program regulations, including the statutory requirement that an employer have a temporary or seasonal need.

Second, for similar reasons, the Department proposes to retain the streamlined procedures and modified definition relating to successors in interest at § 655.103, as well as conforming edits to §§ 651.10, 655.181, 655.182, and 29 CFR 501.20. These provisions provide greater clarity to filers than the prior regulations without placing any additional burden on them. The provisions articulate a clear methodology for determining whether an employer or agent or attorney is a

³³ 87 FR 61660, 61678 (Oct. 12, 2022) (citing § 653.501(c)(1)(iv)(D), (c)(3)(i) and (iv), (c)(5), and (d)(4)).

³⁴ *Id.* (citing §§ 653.501(c)(5) and (d)(4)).

successor-in-interest to a debarred entity, and whether an entity must be considered debarred from the H-2A program. By clarifying and streamlining this regulatory text, employers and agents and attorneys can make an informed decision as to whether they will be considered a debarred entity prior to preparing and submitting an H-2A application. These changes also reduced burdens on the Department and enhanced the Department's ability to protect program integrity.

Third, the Department proposes to retain the explicit prohibition against passport withholding at § 655.135(o), but redesignate the paragraph as § 655.135(m). The withholding of a worker's passport, visa, or other immigration or government identification documents is an egregious restriction of a worker's movements and may be indicative of labor exploitation or trafficking. The Department does not believe that compliance with this provision represents a significant burden to employers because most employers understand the seriousness of such an action—in some circumstances, the withholding of passports, immigration, or identity documents constitutes a criminal offense—and do not withhold worker passports. Given the minimal burden required to comply, and the importance that workers retain in control of their identity documents, the Department believes that current § 655.135(o) should be retained. Doing so will better enable the Department to combat labor exploitation and trafficking.

Fourth, the Department proposes to retain current 29 CFR 501.33(b)(2), introduced by the 2024 H-2A Final Rule, to state that any issue not raised in a party's request for a hearing before the Office of Administrative Law Judges (OALJ) "ordinarily may be deemed waived" in any further proceedings. In the 2024 H-2A Final Rule preambles, the Department explained that issue exhaustion requirements are applicable and appropriate under the H-2A administrative review procedures and, as a result, issues not raised in a request for hearing to the OALJ may be deemed waived. This regulation codifies the Department's current practice, better informs parties of the potential consequences of failing to raise an issue in a request for review, and better preserves agency and judicial resources.

Fifth, the Department proposes to retain the severability provisions implemented by the 2024 H-2A Final Rule at § 655.190 and 29 CFR 510.10. These regulations reflect the Department's position, based on its experience enforcing and administering

the H-2A provisions of the INA, that the regulations can function sensibly in the event that any specific provisions, sections, or applications are invalidated.

Sixth, the Department proposes to retain minor technical fixes made by the 2024 H-2A Final Rule. Specifically, the 2024 Final Rule edited § 655.167(c)(6) to update this paragraph's outdated cross-reference to the regulatory citation for the definition of "work contract." The 2024 Rule also changed § 655.167(c)(7) to add "to" before "DHS."

Seventh, the Department proposes to retain clarifying edits made by the 2024 H-2A Final Rule to 20 CFR 655.122(l)(4) and 20 CFR 655.210(g) with respect to overtime compensation. Specifically, current regulations clarify that, if applicable, the employer must state in the job order: (1) that overtime hours may be available; (2) the wage rate to be paid for any such overtime hours; (3) the circumstances under which overtime hours will be paid; and (4) where the overtime pay is required by law, the applicable Federal, State, or local law requiring the overtime pay. The Department believes that this provision is useful for U.S. workers to understand what benefits are being offered so they may make a reasoned decision as to whether they want the job. The Department solicits comments on this provision, including whether U.S. workers consider overtime benefits when considering whether to accept an agricultural job and, if these benefits are not described in the job order, how applicants may learn about the potential for overtime pay.

The retention of these provisions is consistent with President Trump's E.O. 14192, *Unleashing Prosperity Through Deregulation*, which directs agencies to reduce regulatory burdens and simplify regulations that "are often difficult for the average person or business to understand . . ." and require program users to "synthesiz[e] the collective meaning" of sub-regulatory guidance that was not subject to the Administrative Procedures Act (APA) and for which the Department did not provide notice and opportunity to comment. The rulemaking culminating in the 2024 H-2A Final Rule provided notice and opportunity to comment on long-standing Departmental standards, such as use of the single employer test, and the 2024 H-2A Final Rule responded to those comments and codified the provisions in the regulations, providing clarity to the regulated community and Department's OALJ regarding, for example, the methods the Department uses to determine when two ostensibly distinct employers are, in fact, a single

employer, as necessary to maintain program integrity, reduce instances of misrepresentation and fraud in the nonimmigrant labor certification programs, and ensure fairness for law abiding employers seeking foreign labor certification to fill legitimate labor needs. Similarly, § 655.104 streamlined the successor-in-interest provisions the Department uses across programs, including clearly explaining to the regulated community the factors the Department considers in determining successor-in-interest status and the procedures the Department follows when making such a determination in relation to a notice of debarment from the H-2A program. Finally, the provision explicitly prohibiting passport withholding merely reflects existing employer obligations pursuant to certain Federal, State, and local laws and imposes no new burdens or obligations on employers. Retaining the provision that makes this prohibition explicit in the H-2A program regulations also is consistent with the general aims of President Trump's E.O. 14159, *Protecting the American People Against Invasion*, which declares "it is the policy of the United States to achieve the total and efficient enforcement of [U.S. immigration] laws . . ." and directs agencies to prioritize "enforcement of the provisions of the INA and other Federal laws related to the illegal entry and unlawful presence of aliens in the United States and the enforcement of the purposes of this order," including "dismantl[ing] cross-border human smuggling and trafficking networks . . ."

J. Wagner-Peyser Act

The Department proposes to rescind some provisions adopted in the 2024 H-2A Final Rule that are not necessary for the efficient functioning of the ES. The Department proposes to rescind requirements at §§ 658.503 and .504 relating to the ES-system-wide effect of SWA determinations to discontinue services to employers and notification to the ETA Office of Workforce Investment (OWI) regarding discontinuation and reinstatement, as well as at § 653.501(b)(4), which requires ES staff to consult the OWI discontinuation of services list prior to placing a job order in intra-state or inter-state clearance. Requirements for this list were established to ensure that a final decision to discontinue services to an employer would prohibit an employer from receiving any services from the ES system, not just from offices in the State that discontinued services, enabling States to meet the requirements of § 658.503(e). Ongoing litigation in

multiple jurisdictions prevents this nationally-scoped provision from taking effect, and because each State is responsible for issuing its own discontinuation determinations under part 658, subpart F, the Department believes it is appropriate for these actions to be effective only in the States in which they are issued. The Department proposes to revise § 653.501(b)(4) and paragraphs (i) and (ii) so that the State receiving the clearance order will not provide ES services to an employer for which it has already discontinued services, to remove references to a national OWI discontinuation of services list, and to rescind § 658.504(d) (while retaining clarifying changes to § 658.504 broadly). The Department also proposes to rescind changes to §§ 658.502(b) and 658.503(b) from the 2024 H–2A Final Rule that removed employers' option for pre-final determination hearings and allow employers to request a hearing only after the State makes a final determination. This change was intended to ensure a complete record of decision-making on appeal, but might have limited employers' options for appeal and introduced delay for employers seeking a hearing, and the Department is proposing to restore the option to request a hearing at § 658.502 to provide maximum process to employers using the ES system. Similarly, with regard to the basis for determining the necessity of immediate discontinuation without going through regular procedures, the Department proposes to retain only the basis that existed prior to the 2024 H–2A Final Rule. Any exceptions to a State following regular procedures should be narrow, and a lower threshold for immediate discontinuation raises the risk of insufficiently supported and erroneous decisions adversely impacting employers seeking to recruit workers. The Department invites comments on the balance between State need to act quickly in exceptional circumstances and due process for employers.

The Department proposes to retain certain provisions adopted in the 2024 H–2A Final Rule that clarify long-standing, but previously confusing, discontinuation of services provisions and align standards for foreign workers and U.S. workers rather than disadvantaging U.S. workers, and is soliciting public comment as to whether the following provisions should be retained or modified. As discussed above, the Department proposes to maintain definitions in § 651.10 for “agent,” “farm labor contractor,” and

“successor in interest.” The Department also proposes to maintain definitions that make the ES regulations more readable and understandable and that more clearly define concepts that previously were discussed in the ES regulations yet not adequately defined. These include “criteria clearance order,” “discontinuation of services,” “employment-related laws,” “joint employer,” “non-criteria clearance order,” and “week.” The Department sought to align these new definitions with the same or similar definitions throughout the rule.

The Department proposes to retain a provision at § 653.501(b)(4)(i) that requires States to consult the OFLC and WHD debarment lists and discontinue services to any employer debarred from participating in the H–2A or H–2B foreign labor certification programs. Consistent with an America First policy direction, this provision ensures that U.S. workers are protected from the narrow set of employers the Department has already found to have committed significant violations sufficient to justify their debarment from the labor certification program.

The Department proposes to revert requirements in § 653.501(c)(1)(iv)(E) for listing wages on clearance orders, as the change to this provision in the 2024 H–2A Final Rule was made for consistency with H–2A regulations prescribing wage rate requirements, which the Department proposes above to revert. The Department also proposes to revert provisions in § 653.501(c) and (d) relating to employer obligations in the event of a delay in the start of work, from the current provisions to those that were in effect prior to the 2024 H–2A Final Rule. The current provisions require employers to notify workers in the event of a delay, and in the event of less than 10 days' notice, impose requirements on employers relating to the provision of housing, as well as compensation and benefits for up to 14 days. In order to reduce the financial burden that these regulations impose on employers, which is in addition to the burden caused by work delays, the Department proposes to revert to a guarantee of one week's pay for workers recruited through the ES system in the event of a short-notice delay, and to require SWAs to notify workers of delays and other changed circumstances. The prior provisions appropriately allocated the burden-sharing between employers, workers, and the ES system.

Lastly, the Department proposes to retain certain clarifying changes in §§ 658.501 and 658.502, and the

changes in § 658.503 related to discontinuation of services. The changes in §§ 658.501(a) and 658.502(a) include clarifying changes related to discontinuing services on the bases of debarment from foreign labor certification programs or, as in § 658.501(b), fraud in those programs. The changes in § 658.502(a) require states to more thoroughly document and communicate the bases for discontinuation and the basic facts of the alleged violation, and they give greater clarity and protection to employers in submitting rebuttal evidence and information to the SWA. Discontinuations of service require a high bar and are rare, yet previous to the 2024 H–2A Final Rule, State discontinuations of service sometimes lacked sufficient documentation to explain to employers the basis of a discontinuation, making it difficult for employers to remedy the violation. These provisions ensure States discontinue services only upon thorough review and documentation of violations. Similarly, the Department proposes to retain 2024 H–2A Final Rule changes in §§ 658.503(a), (c), (d) and (f) that clarify processes States must follow prior to discontinuing services, particularly the full documentation and notification required before a discontinuation can take effect. In § 658.503(b), the 2024 H–2A Final Rule describes previously existing requirements for when immediate discontinuation is appropriate, and adds requirements that the State document the facts that led to the immediate discontinuation and notify employers of the details of the discontinuation and their ability to request a hearing. The Department proposes to retain these provisions, in order to ensure employers have adequate information and opportunity to respond, in furtherance of affording maximum process to employers participating in the ES. However, the Department proposes to rescind changes that limited access to a hearing and supported the OWI discontinuation of services list. In § 658.503(e), the Department proposes to retain provisions that explain what discontinuation of services means operationally, so that States and employers understand the process, and proposes to rescind language that refers to nation-wide impact of discontinuation of services, consistent with rescissions described earlier.

III. Administrative Information

A. Executive Order 12866: Regulatory Planning and Review, Executive Order 13563: Improving Regulation and Regulatory Review, and 14192 (Unleashing Prosperity Through Deregulation)

Under E.O. 12866, the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) determines whether a regulatory action is significant and, therefore, subject to the requirements of the Executive Order and review by OMB. Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Section 3(f) of E.O. 12866 defines 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 \$100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or

the principles set forth in the Executive Order. OIRA has reviewed this rule and designated it a significant regulatory action under E.O. 12866.

E.O. 13563 directs agencies to, among other things, propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; the regulation is tailored to impose the least burden on society, consistent with achieving the regulatory objectives; and in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. Improving Regulation and Regulatory Review, 76 FR 3821, 3821 (Jan. 21, 2011), E.O. 13563 recognizes that some costs and benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitative values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts. *Id.*

Executive Order 14192, titled “Unleashing Prosperity Through Deregulation,” was issued on January 31, 2025. This rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action.

Outline of the Analysis

Section III.A.1 describes the need for the rule. Section III.A.2 describes the

process used to estimate the cost savings of the rule and the general inputs used, such as wages and number of affected entities. Section III.A.3 explains how the provisions of the rule will result in quantified costs and transfer payments and presents the calculations the Department used to estimate them. Section III.A.4 describes the quantified and unquantified transfer payments and benefits of the rescissions contained within this proposed rule. Section III.A.5 summarizes the estimated first-year and 10-year total and annualized costs and transfer payments of the rule.

Summary of the Analysis

The Department estimates that all the rescissions contained in this proposed rule will result in a significant reduction in costs, or otherwise create cost savings, as well as transfers of payments from employees to employers. As shown in Exhibit 1, the proposed rule is expected to have an annualized quantifiable net cost savings of \$1.02 million and a total present value 10-year quantifiable net cost savings of \$10.18 million, each at a discount rate of 7 percent.³⁵ The proposed rule is estimated to result in annualized quantifiable transfer payments from H-2A employees to H-2A employers of \$12.66 million and present value 10-year transfer payments of \$88.92 million at a discount rate of 7 percent.³⁶

EXHIBIT 1—ESTIMATED MONETIZED NET COST SAVINGS AND TRANSFER PAYMENTS OF THE PROPOSED RULE
[2022 \$Millions]

	Net cost savings	Transfer payments
Undiscounted 10-Year Total	\$15.35	\$123.42
10-Year Present Value with a Discount Rate of 3%	12.77	106.46
10-Year Present Value with a Discount Rate of 7%	10.18	88.92
10-Year Average	1.54	12.34
Annualized at a Discount Rate of 3%	1.28	12.48
Annualized with at a Discount Rate of 7%	1.02	12.66

The total quantifiable cost of the rule is associated with rule familiarization and the provisions requiring additional information disclosure on the H-2A Applications. Transfer payments are the results of the elimination of the immediate effective date for the updated AEWRs, as described below. The Department also notes that there are unquantifiable cost savings associated with the rescission of certain provisions of the 2024 H-2A Final Rule. For example, there are unquantifiable cost savings to employers that no longer

need to spend time inspecting whether each worker has chosen to use their seatbelt prior to transporting workers and does not have to potentially assign a supervisor to each vehicle to enforce seatbelt usage.

1. Need for Regulation

As previously discussed and in light of these district court injunctions and the Administration’s policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America’s

economic prosperity and national security and the highest possible quality of life for each citizen, the Department has determined that the regulatory requirements and policies contained in the 2024 H-2A Final Rule must be reconsidered and proposes revisions in this NPRM. Specifically, the 2024 H-2A Final Rule adopted a number of unnecessary, burdensome, and costly requirements on employers. Specifically, these provisions include, but are not limited to, substantial new requirements associated with the

³⁵ The rule will have an annualized quantifiable cost of \$1.28 million and a present value 10-year quantifiable cost of \$12.77 million at a discount rate of 3 percent in 2022 dollars.

³⁶ The rule will have annualized quantifiable transfer payments from H-2A employees to H-2A employers of \$12.48 million and total 10-year

transfer payments of \$106.46 million at a discount rate of 3 percent in 2022 dollars.

material terms and conditions offered by employers to H-2A workers that are not commonly provided to other U.S. workers, including progressive discipline policies for cause-based employment terminations, anti-retaliation measures for certain workers engaged in concerted activities, and expanding the authority and scope for a State Workforce Agency to discontinue employment services to an employer that effectively debar an employer from accessing the H-2A program without sufficient due process.

Further, the final rule imposed extensive data collection requirements on employers related to their use of foreign labor recruiters, including personal names and addresses abroad, and detailed personal information associated with all owners of the employers, operators the place(s) of employment, and supervisor(s) and manager(s) of workers employed under the terms of the work contract, often with limited or no practical utility to agency decision making. Thus, the Department has determined that the proposals outlined below will return the H-2A program's regulatory framework to a more reasonable balance between the statute's competing goals of providing an adequate labor supply and protecting the jobs of domestic agricultural workers.

2. Analysis Considerations

The Department estimated the cost savings and transfer payments of this proposed rule relative to the existing baseline (*i.e.*, the current practices for complying, at a minimum, with the H-2A program as currently codified at 20 CFR part 655, subpart B, and 29 CFR part 501).

In accordance with the regulatory analysis guidance articulated in OMB's Circular A-4³⁷ and consistent with the Department's practices in previous rulemakings, this regulatory analysis focuses on the likely consequences of the proposed rule (*i.e.*, costs, benefits, and transfer payments that accrue to entities affected). The analysis covers 10 years (from 2025 through 2034) to ensure it captures measurable costs and transfer payments that accrue over time. The Department expresses all quantifiable impacts in 2022 dollars and uses discount rates of 3 and 7 percent, pursuant to Circular A-4 published on October 9, 2003.

Exhibit 2 presents the number of affected entities that are expected to be

impacted by this proposed rule.³⁸ The average number of affected entities is calculated using OFLC H-2A certification data from FY 2016 through FY 2022. Exhibit 3 presents the number of workers who are expected to be impacted by this proposed rule. The exhibit contains the number of certified H-2A workers from FY 2012 through FY 2022.

EXHIBIT 2—NUMBER OF UNIQUE EMPLOYERS BY YEAR

FY	Number
2016	6,713
2017	7,187
2018	7,902
2019	8,391
2020	7,785
2021	9,442
2022	10,571
Average	8,284

EXHIBIT 3—HISTORICAL H-2A PROGRAM DATA

FY	Workers certified
2012	85,248
2013	98,814
2014	116,689
2015	139,725
2016	165,741
2017	199,924
2018	242,853
2019	258,446
2020	275,430
2021	317,619
2022	371,619

a. Growth Rate

The Department estimated growth rates for certified H-2A workers based on program data presented in Exhibit 3 and estimated growth rates for unique H-2A employers based on program data presented in Exhibit 2.

The compound annual growth rate (CAGR) for certified H-2A workers using the program data in Exhibit 3 is calculated as 15.9 percent. This growth rate, applied to the analysis timeframe of 2025 to 2034, would result in more H-2A certified workers than projected employment of workers in the relevant H-2A SOC codes by BLS.³⁹ Therefore,

³⁸ OFLC, *Performance Data*, <https://www.dol.gov/agencies/eta/foreign-labor/performance> (last visited Feb. 8, 2024).

³⁹ Comparing BLS 2032 projections for combined agricultural workers (SOC 45-2000) with a 14.8-percent growth rate of H-2A workers yields estimated H-2A workers about 178 percent greater than BLS 2032 projections. The projected workers for the agricultural sector were obtained from BLS's Occupational Projections and Worker Characteristics, <https://www.bls.gov/emp/tables/occupational-projections-and-characteristics.htm>.

to estimate realistic growth rates for the analysis, the Department applied the growth rate for unique employers, assuming the growth rate for unique employers and workers should be similar. The Department used FY 2016–2022 data on unique employers, where the use of FY 2016 as the first year is due to data availability on calculated unique employers. The Department calculated a CAGR based on FY 2016 unique employers (6,713) and the FY 2022 unique employers (10,571). The result is an estimate of 7.9 percent.⁴⁰

The estimated annual growth rates for unique employers (7.9 percent) and workers (7.9 percent) were applied to the estimated cost savings and transfers of this proposed rule to forecast participation in the H-2A program.⁴¹

b. Compensation Rates

In Section VIII.A.3, the Department presents the measurable cost savings, including labor, associated with the implementation of the provisions of the rule. Exhibit 4 presents the hourly compensation rates for the occupational categories expected to experience a change in the number of hours necessary to comply with all the rescissions contained in this proposed rule. The Department used the mean hourly wage rate for a private sector HR Specialist (SOC code 13-1701).⁴² Wage rates are adjusted to reflect total compensation, which includes nonwage factors such as overhead and fringe benefits (*e.g.*, health and retirement benefits). We use an overhead rate of 17 percent⁴³ and a fringe benefits rate based on the ratio of average total compensation to average wages and salaries in 2022.⁴⁴ We then multiply the loaded wage factor by the wage rate to calculate an hourly compensation rate. The Department used the hourly compensation rates presented in Exhibit

⁴⁰ Calculation: $7.9\% = (10,571 \div 6,713)(1 \div 6) - 1$.

⁴¹ Proposed forecasted estimates of H-2A employer participation: 11,419 in 2023; 12,335 in 2024; 13,325 in 2025; 14,394 in 2026; 15,548 in 2027; 16,796 in 2028; 18,143 in 2029; 19,599 in 2030; 21,171 in 2031; and 22,869 in 2032.

⁴² BLS, *National Occupational Employment and Wage Estimates: 13-1701* (May 2021), <https://www.bls.gov/oes/current/oes131701.htm> (last visited Feb. 8, 2024).

⁴³ Cody Rice, U.S. Envtl. Prot. Agency, *Wage Rates for Economic Analyses of the Toxics Release Inventory Program 7* (June 10, 2002), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0005>.

⁴⁴ BLS, News Release, *Employer Costs for Employee Compensation—December 2022* (Mar. 17, 2023), https://www.bls.gov/news.release/archives/eccec_03172023.pdf. Ratio of total compensation to wages and salaries for all private industry workers: $40.23 \div 28.37 = 1.418$.

³⁷ OMB Circular No. A-4, *Regulatory Analysis* (2003).

4 throughout this analysis to estimate the labor costs for each provision.

EXHIBIT 4—COMPENSATION RATES
[2022 Dollars]

Position	Grade level	Base hourly wage rate	Loaded wage factor	Overhead costs	Hourly compensation rate
	(a)	(b)	(c)	(d)	(d = a + b + c)
HR Specialist	N/A	\$35.13	\$14.75 (\$35.13 × 0.42)	\$5.97 (\$35.13 × 0.17)	\$55.79

3. Analysis of Quantified Costs, Cost Savings, and Transfers

The Department's analysis below covers the estimated cost savings and transfer payments associated with the baseline requirements (*i.e.*, 2024 H-2A Final Rule) compared to the rescissions under this proposed rule. In accordance with Circular A-4, the Department considers transfer payments as payments from one group to another that do not affect total resources available to society. This final rule estimated the cost of rule familiarization and application additions and transfer payments associated with the elimination of the delayed effective date for updated AEWRs.

a. Quantified Costs and Cost Savings

The following sections describe the quantified costs and cost savings associated with employers having to read and understand this proposed rulemaking, not having to read and understand the 2024 H-2A Final Rule, and the rescission of the provisions requiring additional information disclosure on the H-2A Application.

i. Rule Familiarization

Under this proposed rule, H-2A employers will incur costs to familiarize themselves with the impact of the rescissions of requirements contained in the 2024 H-2A Final Rule. New employers in each subsequent year will now save time and costs trying to familiarize themselves with current requirements relative to the requirements they would have needed to familiarizing themselves with if the 2024 H-2A Final Rule were still in effect.

To estimate the costs and cost savings, the Department applied the growth rate of H-2A employers (7.9 percent) to the number of unique H-2A employers (8,284) to determine the number of unique H-2A applicants impacted in the first year. For subsequent years, the number of new employers was estimated by multiplying the previous year's employer count by the growth

rate of H-2A employers (7.9 percent) and then subtracting that value from the previous year's total employer count. Exhibit 5 details the number of new employers for each year of the analysis.

EXHIBIT 5—NUMBER OF NEW EMPLOYERS BY YEAR

FY	Total employers	New employers
2025	8,938	N/A
2026	9,645	706
2027	10,406	762
2028	11,229	822
2029	12,116	887
2030	13,073	957
2031	14,106	1,033
2032	15,220	1,114
2033	16,422	1,202
2034	17,720	1,297

For the initial costs, the number of unique H-2A employers in the first year (8,938) was multiplied by the estimated amount of time required to review this rule (1 hour). This number was then multiplied by the total compensation rate of an HR specialist, as described above in Exhibit 4 (\$55.79 per hour). This calculation results in a total undiscounted cost of \$498,651 during the first year.

The Department estimated that the 2024 Final Rule would require H-2A employers to incur four hours of rule familiarization costs. Rescinding the 2024 Final Rule will remove those four hours of rule familiarization costs. Accounting for the one hour of rule familiarization associated with this rulemaking, the net effect is a reduction of three hours of rule familiarization costs in FY 2026–2034. Using the same total compensation rate of an HR specialist as above, this produces an undiscounted cost savings of \$1,469,509 during FY 2026–2034 and an undiscounted net cost savings of \$970,858 over the 10 years after the rule takes effect. Combining the FY 2025 costs with the FY 2026–2034 cost savings, the annualized net cost savings over the 10-year period are \$73,188 and

\$49,478,479,217 at discount rates of 3 and 7 percent, respectively.

ii. Additional Information Disclosure on the H-2A Application

Under the 2024 H-2A Final Rule, H-2A employers are required to submit additional information on the H-2A Application, which imposed a yearly cost as the time associated with filling out this information is required for every application for certification. The additional information includes the names, addresses, business phone numbers, and dates of birth for the owner(s) of each employer, each operator of the place(s) of employment, and all managers and supervisors of workers employed under the H-2A Application; DBA information; and information about the identity and location of any foreign labor recruiter the employer engaged, directly or indirectly, in international recruitment, as well as all persons and entities hired by or working for the recruiter or agent, and any of the agents or employees of those persons and entities.

To estimate the annual cost savings associated with proposed rescissions of the application additions contained in this rule, the Department applied the growth rate of H-2A employers (7.9 percent) to the current number of unique certified H-2A employers (8,938) to determine the number of unique H-2A employers in the first year (8,938). The number of unique certified H-2A employers in the first year is then multiplied by the growth rate again to determine the number of unique certified H-2A employers in the second year. This process is repeated each year to determine the total number of unique certified H-2A employers every year during the study period. Since it is assumed that only a single HR specialist per employer will incur the additional time investment, the estimated total yearly cost can be calculated by multiplying the total number of unique certified H-2A employers (8,938) by the HR specialist hourly wage rate (\$35.13 per hour), the loaded wage factor and

the overhead rate for the private sector (1.59), and the estimated additional time taken to gather and enter the information on a yearly basis (2 hours on average). Lastly, this value is multiplied by the growth rate of unique employers (7.9 percent) to the n th power, with n being equal to the period year. The result is \$997,302 in cost savings in the first year, an undiscounted average over a 10-year period of \$1,437,987 in cost savings, and discounted annualized savings of \$1,204,219, and \$968,193 at rates of 3 and 7 percent, respectively.

b. Transfer Payments and Benefits

The following section describes the quantified and unquantified transfer payments and benefits of the rescissions contained within this proposed rule and describes the practical utility of the Department's disclosure of unquantified transfer payments and qualitative benefits associated with the 2024 Final Rule.

i. Quantified Transfer Payments

This section discusses the quantifiable transfer payments related to the elimination of the immediate effective date for the AEWR publication. The Department considers transfers as payments from one group to another that do not affect total resources available to society. The transfers measured in this analysis are wage transfers from H-2A workers to U.S. employers. H-2A workers are migrant workers who will spend some of their earnings on consumption goods in the U.S. economy but likely send a large fraction of their earnings to their home countries.⁴⁵ Therefore, the Department

considers the wage transfers in the analysis as transfer payments within the global economic system.

A. Elimination of the Immediate Effective Date for Updated AEWRs

Under the 2024 H-2A Final Rule, the Department publishes the AEWR as soon as data are available, typically in the middle of December for AEWRs based on FLS data and which has an immediate effective date.⁴⁶ Under this proposed rule, the Department intends to return to its practice of providing a 2-week delay until the AEWR is effective, typically January 1st of the following year. As noted previously, this brief period provides time for employers to adjust their payroll systems and to make business decisions related to these changed costs in labor, which are particularly significant for employers planting, cultivating, and harvesting specialty crops where labor costs are often 30 to 40 percent of total operating cost. Reinstating the 2-week delay until the AEWR is effective means, employers that employ workers during the 2-week period from mid-December to early January will no longer experience a wage transfer to employees due to the elimination of the immediate effective date of the updated AEWRs.

To estimate the transfer associated with wages from employees to H-2A employers, the Department first uses FY 2020 and FY 2021 H-2A certification data to calculate the weighted average increase in AEWR from one year to the next.⁴⁷ The Department weights the average by the number of workers in each State with employment between

December 14th and the end of the year to account for regional differences in employment during December. The result is an average increase in the AEWR by \$1.09.⁴⁸ The Department then calculates the average number of days worked between December 14th and the end of the year (11.87) using the FY 2020 and FY 2021 H-2A certification data. The Department estimates the average annual number of workers with work during this period using the H-2A certification data (89,208).⁴⁹

The Department determines the total amount of the transfers by multiplying the 2-year weighted AEWR difference for end-of-year employment (1.09), the 2-year average number of days worked between December 14th and the end of year (11.87), the average number of work hours in a day (7.4),⁵⁰ and the number of H-2A workers during this period (89,208). To determine the transfers for every year in the 10-year period, the total number of H-2A workers during the period is multiplied by the growth rate of H-2A workers (7.9 percent). The same process is repeated each year in the period. The total undiscounted average annual transfers associated with this provision is \$12,342,109 and the discounted annualized transfers are \$12,480,377 and \$12,660,319 at discount rates of 3 and 7 percent, respectively. The Department also conducted a sensitivity

⁴⁸ Because FY 2020 and FY 2021 H-2A certification data do not reflect the wage increases due to the 2023 AEWR Final Rule, as explained in a previous footnote, the transfer payments estimated in the analysis are likely understated in that they may not account for the main change under that rule, namely the limited job opportunities that would be subject to updated AEWRs based on the OEWS data. See 88 FR at 12764–65. The 2023 AEWR Final Rule became effective on March 30, 2023, and, therefore, the Department does not have any readily available FY H-2A certification data to estimate wage transfer payments after the publication of the 2023 AEWR Final Rule. The Department, moreover, sought public comment on how these wage transfer impacts can be calculated but received no comments. However, the 2023 AEWR Final Rule explained that the Department anticipates a very limited number of H-2A job opportunities would be subject to the OEWS-based AEWR, as the majority of H-2A job opportunities are and will continue to remain subject to FLS-based AEWRs. See 88 FR at 12766, 12799. As such, the Department considers the impacts of the potential underestimation here to be *de minimis* because of the low incidence of job opportunities assigned the OEWS AEWR pursuant to the 2023 AEWR Final Rule.

⁴⁹ The Department uses the growth rate of H-2A workers (7.9 percent) to produce proposed forecasted estimates of H-2A workers: 96,247 in 2023; 103,840 in 2024; 112,033 in 2025; 120,873 in 2026; 130,410 in 2027; 140,699 in 2028; 151,800 in 2029; 163,777 in 2030; 176,699 in 2031; and 190,641 in 2032.

⁵⁰ The Department analyzed FY 2020 and FY 2021 certification data for end-of-year employers that reported anticipated hours per day, resulting in an average of 7.4 hours per day.

⁴⁵ Elimination of the immediate effective date for updated AEWRs will also result in wage transfers from workers in corresponding employment to U.S. employers, but the Department is not able to quantify this transfer due to the lack of data for workers in corresponding employment and their wages. In particular, the Department does not collect or possess sufficient information about the number of corresponding workers affected and their wage payment structures to reasonably measure the transfers to corresponding workers. Employers are not required to provide the Department, on any application or report, the estimated or actual total number of workers in corresponding employment. Although each employer, as a condition of being granted a temporary agricultural labor certification, must provide the Department with a report of its initial recruitment efforts for U.S. workers, including the name and contact information of each U.S. worker who applied or was referred to the job, such information typically reflects only a very small portion of the total recruitment period, which runs through 50 percent of the certified work contract period, and does not account for any other workers who may be considered in corresponding employment and already working for the employer. Because the report of initial recruitment efforts for U.S. workers only captures information from a limited portion of the recruitment period and does not account for workers already employed by the

employer who may be in corresponding employment, the Department is not able to draw on this information to meaningfully assess the total number of corresponding workers affected or their wage payment structures, without which the Department is unable to reasonably measure the transfers from corresponding workers. The Department has consistently sought public comment on how these wage transfer impacts can be calculated but consistently receives no comments.

⁴⁶ New AEWRs based on OEWS data currently become effective on or around July 1st for the small percentage of job opportunities that cannot be encompassed within the SOC codes for AEWRs that are based on the FLS field and livestock workers (combined) data. The use of OEWS data to calculate AEWRs in limited circumstances was the result of a change made under the Department's 2023 AEWR Final Rule. See 88 FR 12760, 12764–65 (Feb. 28, 2023). The analysis here is limited to FY 2020 and FY 2021 H-2A certification data, during which period the AEWR was calculated based only on FLS data, and thus, the analysis focuses on the 2-week period from mid-December to early January that is associated with the publication and effective dates of FLS-based AEWRs under current practice.

⁴⁷ OFLC, *Performance Data*, <https://www.dol.gov/agencies/eta/foreign-labor/performance> (last visited June 18, 2025).

analysis using the CAGR of 15.9 percent for H-2A workers. The resulting total undiscounted average annual transfers is \$18,135,595, and the discounted annualized transfers are \$18,037,709 and \$17,901,328 at discount rates of 3 and 7 percent, respectively.

ii. Unquantified Transfer Payments and Benefits

In the 2024 H-2A Final Rule, the Department did not provide any measurable estimates of benefits associated with the major regulatory requirements impacting employers who seek to employ H-2A workers. The Department consistently noted that it lacked any data regarding the prevalence of certain conditions (*e.g.*, number of workers impacted by work start date delays, frequency of employers paying higher piece rates, transportation related accidents) to make measurable determinations regarding the benefits of certain provisions of the 2024 H-2A Final Rule. In fact, no measurable wage transfers were estimated for employers who

would otherwise have to compensate workers based on untimely notifications of a change in the work start date or even payments of piece rate wages, because no evidence was presented that such requirements were necessary due to any prevalence of employer non-compliance with the regulatory requirements in effect before the 2024 Final Rule was promulgated.

Rather, the Department made general and unsubstantiated qualitative statements noting that certain provisions ensure workers are not “deprived of their rights using inconsistent or unfair practices” (*i.e.*, due to unjustified terminations for cause) or “should increase workers’ dignity and safety” or “should help ensure that workers under the H-2A program can assert their rights without the unique risks associated with retaliation” (*e.g.*, protection for worker advocacy and self-organization) or “safeguards the health, safety, and dignity of those workers and also prevents the depression of working conditions for the local agricultural

workforce.” Thus, in the absence of benefits that can offer some degree of measurable balance to the quantified costs, the Department initially concludes that the expected unrecoverable compliance and transfer costs associated with the 2024 H-2A Final Rule far outweigh its expected unquantifiable transfers and benefits, which this proposed rule seeks to better balance based on the clear statutory mandates enacted by Congress for the Secretary of Labor.

5. Summary of the Analysis Concerning Costs, Cost Savings, and Transfers

Exhibit 6 summarizes the estimated total quantifiable cost savings and transfer payments of this final rule over the 10-year analysis period. The Department estimates the annualized net cost savings from the rescissions in this proposed rule \$1.02 million and the annualized transfer payments (from employees to H-2A employers) at \$12.66 million, each at a discount rate of 7 percent.

EXHIBIT 6—ESTIMATED MONETIZED COST SAVINGS AND TRANSFER PAYMENTS OF THIS PROPOSED RULE
[2022 \$Millions]

	Net cost savings	Transfer payments
2024	\$0.50	\$8.56
2025	1.19	9.24
2026	1.29	9.97
2027	1.39	10.76
2028	1.50	11.60
2029	1.62	12.52
2030	1.75	13.51
2031	1.88	14.57
2032	2.03	15.72
2033	2.19	16.96
Undiscounted 10-Year Total	15.35	123.42
10-Year Total with a Discount Rate of 3%	12.77	106.46
10-Year Total with a Discount Rate of 7%	10.18	88.92
10-Year Average	1.54	12.34
Annualized with a Discount Rate of 3%	1.28	12.48
Annualized with a Discount Rate of 7%	1.02	12.66

Alternatives Considered

The Department considered two alternatives to this proposal. First, the Department considered the alternative of preserving the current regulations at 20 CFR parts 651, 653, 655, and 658, and 29 CFR part 501, as modified by the 2024 H-2A Final Rule, until litigation is resolved. This alternative was rejected because of the multiple court decisions preventing the Department from enforcing parts of the regulations as currently codified. The different court orders place different limitations on the Department’s enforcement scheme (*e.g.*, some provisions are enjoined in some

localities but not in others), which results in a confusing patchwork of regulatory requirements throughout the country. Retaining current 20 CFR parts 651, 653, 655, and 658, and 29 CFR part 501, as modified by the 2024 H-2A Final Rule, would be confusing and cumbersome for employers using the H-2A program to understand which provisions apply to them. Second, the Department considered reverting back to the regulations in 20 CFR parts 651, 653, 655, and 658, and 29 CFR part 501, as of June 27, 2024. This option would remove all changes effectuated by the 2024 H-2A Final Rule, regardless of

their utility. The Department rejected this option because it believes that some of the provisions adopted in the 2024 H-2A Final Rule that merely codified existing practice, streamlined procedures and imposed no additional burdens on stakeholders may be worth retaining. The Department invites comments on these two regulatory alternatives, as well as other regulatory alternatives that commenters may propose.

B. Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act and Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601 *et seq.*, as amended by the *Small Business Regulatory Enforcement Fairness Act of 1996*, Public Law 104–121, requires agencies to determine whether regulations will have a significant economic impact on a substantial number of small entities. The Department certifies that the recission proposed in this rulemaking does not have a significant economic impact on a substantial number of small entities. The Department presents the basis for this certification in the analysis below.

1. Description of the Number of Small Entities to Which This Proposed Rule Will Apply

a. Definition of Small Entity

The RFA defines a “small entity” as a (1) small not-for-profit organization, (2) small governmental jurisdiction, or (3) small business. The Department used the entity size standards defined by the Small Business Administration (SBA),

in effect as of December 19, 2022, to classify entities as small.⁵¹ SBA establishes separate standards for individual 6-digit North American Industry Classification System (NAICS) industry codes, and standard cutoffs are typically based on either the average number of employees, or the average annual receipts. Small governmental jurisdictions are another noteworthy exception. They are defined as the governments of cities, counties, towns, townships, villages, school districts, or special districts with populations of less than 50,000 people.⁵²

b. Number of Small Entities

Given that the 2024 H–2A Final Rule was promulgated and became effective on June 28, 2024, only one year ago, the Department initially concludes that the employment and annual revenue data from the business information provider Data Axle,⁵³ which was merged with the H–2A labor certification records maintained by OFLC for FY 2020 and FY 2021, remains valid for analytical use in this proposed rulemaking. This process allows the Department to identify the number and type of small entities in the H–2A certification data as well as provide reasonable estimates of

their annual revenues. Based on these data sources, the Department determined the number of unique employers in the FY 2020 and FY 2021 certification data based on the employer name and city. The Department identified 9,927 unique employers (excluding labor contractors). Of those 9,927 employers, the Department was able to obtain data matches of revenue and employees for 2,615 H–2A employers in the FY2020 and FY2021 labor certification data.

Of those 2,615 employers, the Department determined that 2,159 were small (82.5 percent). These unique small entities had an average of 11 employees and average annual revenue of approximately \$3.6 million. Of these small unique entities, 2,139 of them had revenue data available from Data Axle. The Department’s analysis of the impact of this proposed rule on small entities is based on the number of small unique entities (2,139 with revenue data).

To provide clarity on the agricultural industries impacted by this proposed rule, Exhibit 7 shows the number of unique H–2A small entities employers with certifications in the FY 2020 and FY 2021 labor certification data within each NAICS code at the 6-digit level.

EXHIBIT 7—NUMBER OF H–2A SMALL EMPLOYERS BY NAICS CODE

6-Digit NAICS	Description	Number of employers	Percent	Size standard
111998	All Other Miscellaneous Crop Farming	611	29	\$2.5 million.
444240	Nursery, Garden Center, and Farm Supply Stores	162	8	\$21.5 million.
561730	Landscaping Services	135	6	\$9.5 million.
445230	Fruit and Vegetable Markets	127	6	\$9.0 million.
424480	Fresh Fruit and Vegetable Merchant Wholesalers	78	4	100 employees.
111339	Other Noncitrus Fruit Farming	78	4	\$3.5 million.
112990	All Other Animal Production	57	3	\$2.75 million.
424930	Flower, Nursery Stock, and Florists' Supplies Merchant Wholesalers	47	2	100 employees.
424910	Farm Supplies Merchant Wholesalers	39	2	200 employees.
484230	Specialized Freight (except Used Goods) Trucking, Long-Distance	37	2	\$34.0 million.
	All Other	768	36	
	Total	2,139	100	

The Department also collected employment and annual revenue data for the NAICS Agricultural major industry⁵⁴ from SUSB⁵⁵ and merged those data into the estimated costs for small businesses from the H–2A certification data for FY 2020 and FY 2021. The Department assumes that NAICS sectors related to H–2A employment (1112, 1113, 1114, 1121,

1122, 1123, 1124, 1125, and 1129) have similar representation in size distribution as the broader 2-digit industry. The Department believes it is a reasonable assumption for the analysis because the broader 2-digit industry completely covers the 4-digit NAICS industries (1112, 1113, 1114, 1121, 1122, 1123, and 1129). The size distribution in the broader 2-digit

industry mirrors the average size distribution in the 4-digit NAICS industries (1112, 1113, 1114, 1121, 1122, 1123 and 1129). No small businesses are left out for estimating impact on small entities in the affected NAICS industries. This assumption allows the Department to conduct a robust analysis of the most inclusive set of small businesses, which includes the

⁵¹ SBA *Table of Small Business Size Standards Matched to North American Industry Classification System Codes* (December 19, 2022), <https://www.sba.gov/document/support-table-size-standards>.

⁵² See <https://advocacy.sba.gov/resources/the-regulatory-flexibility-act> for details.

⁵³ Data Axle (Aug. 2023), <https://www.data-axle.com>.

⁵⁴ Due to omissions in collected data, 6-digit and 4-digit NAICS code data were not available. See U.S. Census Bureau, *Economic Census: NAICS Codes Understanding Industry Classification Systems* (Sept. 28, 2023). <https://www.census.gov/>

<https://www.census.gov/programs-surveys/economic-census/year/2022/guidance/understanding-naics.html>.

⁵⁵ See U.S. Census Bureau, *Statistics of U.S. Businesses* (Sept. 19, 2023). <https://www.census.gov/programs-surveys/susb/data.html>.

number of firms, number of employees, and annual revenue by firm size. Using this data allows the Department to estimate the per-provision cost of this final rule as a percent of revenue by firm size.

2. Projected Impacts to Affected Small Entities

The Department estimated the incremental impacts on small entities from the baseline (*i.e.*, the current practices for complying, at a minimum, with the H-2A program as currently codified at 20 CFR part 655, subpart B) to this proposed rule. As discussed in previous sections, the Department estimates impacts using historical certification data and therefore simulates the impacts of the proposed rule to each actual employer in the H-2A program rather than using representative data for employers within a given sector. The Department estimated the costs of (a) time to read and review this proposed rule, (b) time and cost savings associated with rescinding requirements for employers to collect and maintain additional information for the application additions provision and add that information to H-2A applications, and (c) wage transfers associated with rescinding the immediate effective date

from the AEWR publications and reinstituting the agency's practice of permitting a 2-week delay in the effective date. The estimates included in this analysis are consistent with those presented in the E.O. 12866 section.

The Department estimates that 2,139 unique small entities will incur a one-time cost of \$55.79 to familiarize themselves with this proposed rule, based on one hour of an HR Specialist's time, as described above in Exhibit 4. This is an estimated one-time net savings of \$167.37, compared to reading and understanding the 2024 H-2A Final Rule if it once again became effective, which would have required four hours of an HR Specialist's time. Small entities will experience another estimated annual savings of \$111.58 due to the rescission of unnecessary and burdensome requirements to collect and maintain information due to the additional disclosure requirements associated with the 2024 final rule, which had required two hours of an HR Specialist's time.

In addition to the cost of rule familiarization and the cost of information and record keeping due to application additions, each small entity may have savings in wage costs due to the rescission of the immediate effective date requirement of the AEWR. To

estimate the savings associated with this rescission for each small entity, we followed the methodology presented in the E.O. 12866 section. For each certification of a small entity, the Department calculated total wage impacts of this final rule in calendar year (CY) 2020 and CY 2021 based on each certification for employment between December 14th and the end of the year and the annual increase in the AEWR. The Department estimates the wage savings to all small entities at \$826, on average, in the first year.⁵⁶ The Department initially concludes that many small entities will not experience an impact related to this rescission from this final rule because they do not have workers employed at the end of December.

Exhibit 8 shows the estimated cost savings per small entity for each year of the analysis due to this proposed rule. The first-year cost savings per small entity is estimated at \$1,087 at a discount rate of 7 percent. The annualized cost savings per small entity is estimated at \$979 at a discount rate of 7 percent. These estimates are *average costs*, meaning that some small entities will have higher cost savings while other small entities will have lower cost savings, regardless of firm size.

EXHIBIT 8—ESTIMATED COST SAVINGS TO SMALL ENTITIES DUE TO RESCISSIONS

Year	Rescission of rule familiarization costs	Rescission of application additions	Rescission of AEWR immediate effective date	Average total cost savings per employer
1	\$167.37	\$111.71	\$808	\$1,087
2	167.37	111.71	872	1,151
3	167.37	111.71	941	1,220
4	167.37	111.71	1,015	1,294
5	167.37	111.71	1,095	1,374
6	167.37	111.71	1,181	1,460
7	167.37	111.71	1,264	1,543
8	167.37	111.71	1,375	1,654
9	167.37	111.71	1,483	1,762
10	167.37	111.71	1,600	1,879
First-year cost savings (\$), 7% discount rate				1,087
Annualized cost savings (\$), 7% discount rate				979

The Department used the cost per employer analysis in the 2024 H-2A Final Rule as the basis for estimating the cost savings of the rescissions (*i.e.*, or

cost avoidances) in this proposed rule per small entity as a percentage of annual receipts. First, the Department used SBA's Table of Small Business

Size Standards to determine the size thresholds for small entities within the agricultural industry.⁵⁷ Next the Department obtained data on the

⁵⁶ In CY 2020 the average wage impact to all small entities is \$620 in savings, and in CY 2021 it is \$1,032 in savings. Because CY 2020 and CY 2021 H-2A certification data do not reflect the wage increases due to the 2023 AEWR Final Rule, the transfer payments estimated in the analysis are likely understated. As explained in a previous footnote, the transfer payments are likely understated in that they may not account for the main change under the 2023 AEWR Final Rule, namely the limited job opportunities that would be

subject to updated AEWRs based on OEWS data. See 88 FR at 12764–12765. The 2023 AEWR Final Rule explained that the Department anticipates a very limited number of H-2A job opportunities would be subject to the OEWS-based AEWR, as the majority of H-2A job opportunities are and are estimated to continue to remain subject to FLS-based AEWRs. See 88 FR at 12766, 12799. The Department therefore considers the impacts of the potential underestimation to be *de minimis* because

of the low incidence of job opportunities assigned the OEWS AEWR under the 2023 AEWR Final Rule.

⁵⁷ SBA, *Table of Small Business Size Standards Matched to North American Industry Classification System Codes*, (Mar. 17, 2023), <https://www.sba.gov/document/support-table-size-standards>. The size standards, which are expressed in either average annual receipts or number of employees, indicate the maximum allowed for a business in each subsector to be considered small.

number of firms, number of employees, and annual revenue by industry and firm size category from SUSB.⁵⁸ The Department used the Gross Domestic Product deflator to convert revenue data from 2017 dollars to 2022 dollars.⁵⁹ Then, the Department divided the estimated first-year cost and the annualized cost per small business (discounted at a 7-percent rate) by the average annual receipts per firm to determine whether this final rule will have a significant or substantial economic impact on small businesses in each size category. The Department used a total cost estimate of 3 percent of revenue as the threshold for a significant individual impact and set a total of 20 percent of small entities incurring a significant impact as the threshold for a substantial impact on small entities. A threshold of 3 percent of revenues has been used in prior rulemakings for the definition of significant economic impact.⁶⁰ This threshold is also consistent with that sometimes used by other agencies.⁶¹

Finally, when examining the impact of the rescissions contained in this proposed rule on small entities by the proportion of revenue, of the 2,139 unique small entities with revenue data in the FY 2020 and FY 2021 certification data, only 0.7 percent of employers are estimated to have more than 3 percent of their total revenue saved in the first year based on 2020 data and another 2.0 percent of employers are estimated to have more than 3 percent of their total revenue saved in the first year based on 2021 data due to the rescission of these unnecessary regulatory requirements. In addition, no individual NAICS code sector has 20 percent or more of small entities with an impact greater than 3 percent of revenue. Thus, based on this initial analysis, the Department certifies

that this final rule will not impose a significant economic impact on a substantial number of small entities. Rather, the rescissions contained in this proposed rule will provide some cost “relief” to small entities who otherwise would have to absorb additional and unrecoverable compliance costs associated with the requirements, data collection, and record retention mandates imposed by the 2024 H-2A Final Rule.

C. Review Under the Paperwork Reduction Act

The purpose of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*, includes minimizing the paperwork burden on affected entities. The PRA requires certain actions before an agency can adopt or revise a collection of information, including publishing for public comment a summary of the collection of information and a brief description of the need for and proposed use of the information.

As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program to provide the public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the PRA. See 44 U.S.C. 3506(c)(2)(A). This activity helps to ensure that the public understands the Department’s collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

A Federal agency may not conduct or sponsor a collection of information unless it is approved by the Office of Management and Budget (OMB) under the PRA and it displays a currently valid OMB control number. The public is also not required to respond to a collection of information unless it displays a currently valid OMB control number. In addition, notwithstanding any other provisions of law, no person will be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number (44 U.S.C. 3512).

This rulemaking potentially affects specific information collections *Criteria and Non-Criteria Agricultural Clearance Order Forms and H-2A Application for Temporary Employment Certification in States and by Employers Covered by Injunction of the Farmworker Protection*

(OMB 1205–0562), *H-2A Temporary Agricultural Labor Certification Program* (OMB 1205–0466), and *Agricultural Recruitment System Forms Affecting Migratory Farm Workers* (OMB 1205–0134)). Any changes the Department might contemplate making to these collections will be communicated through an upcoming 60-day **Federal Register** Notices. Through these notices, the Department will request public comments that will be later addressed by publishing 30-day **Federal Register** Notices and submitting information collection requests to OMB.

D. Review Under Executive Order 13132

E.O. 13132, *Federalism*, 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The E.O. requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The E.O. also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.

The Department has examined this proposed rescission and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

E. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

The Department has reviewed this proposed rule in accordance with E.O. 13175 and has determined that it does not have tribal implications. This proposed rule does not have substantial direct effects 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 tribal governments.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, “Civil Justice Reform,” imposes on Federal agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear

⁵⁸ U.S. Census Bureau, *Statistics of U.S. Businesses* (May 10, 2022), <https://www.census.gov/programs-surveys/susb/data.html>.

⁵⁹ U.S. Bureau of Economic Analysis, *Table 1.1.9. Implicit Price Deflators for Gross Domestic Product*, <https://apps.bea.gov/iTable/?reqid=19step=2isuri=1categories=survey> (last visited May 30, 2023).

⁶⁰ See, e.g., Final Rule, *Increasing the Minimum Wage for Federal Contractors*, 79 FR 60634, 60706 (Oct. 7, 2014); Final Rule, *Discrimination on the Basis of Sex*, 81 FR 39108, 39151 (June 15, 2016); NPRM, *National Apprenticeship System Enhancements*, 89 FR 3118, 3252 (Jan. 17, 2024).

⁶¹ See, e.g., Final Rule, *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II*, 79 FR 27106, 27151 (May 12, 2014) (Department of Health and Human Services rule stating that under its agency guidelines for conducting regulatory flexibility analyses, actions that do not negatively affect costs or revenues by more than 3 percent annually are not economically significant).

legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of E.O. 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General.

Section 3(c) of E.O. 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOL has completed the required review and determined that, to the extent permitted by law, this proposed rescission meets the relevant standards of E.O. 12988.

G. Review Under the Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4, codified at 2 U.S.C. 1501 *et seq.*) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. UMRA requires Federal agencies to assess a regulation's effects on State, local, and tribal governments, as well as on the private sector, except to the extent the regulation incorporates requirements specifically set forth in law. Title II of the UMRA requires each Federal agency to prepare a written statement assessing the effects of any regulation that includes any Federal mandate in a proposed or final agency rule that may result in \$100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector. A Federal mandate is any provision in a regulation that imposes an enforceable duty upon State, local, or tribal governments, or upon the private sector, except as a condition of Federal assistance or a duty arising from participation in a voluntary Federal program.

The Department examined this proposed rescission according to UMRA and its statement of policy and

determined that the rescission does not contain a Federal intergovernmental mandate, nor is it expected to require expenditures of \$100 million or more in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector. As a result, the analytical requirements of UMRA do not apply.

H. Review Under Executive Order 12630

Pursuant to E.O. 12630, *Governmental Actions and Interference with Constitutionally Protected Property Rights*, 53 FR 8859 (Mar. 18, 1988), the Department has determined that this proposed rescission would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

I. Review Under the Treasury and General Government Appropriations Act, 1999

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

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002). The Department has reviewed this proposed rescission under the OMB and has concluded that it is consistent with applicable policies in those guidelines.

List of Subjects

20 CFR Part 651

Employment, Grant programs—labor.

20 CFR Part 653

Agriculture, Employment, Equal employment opportunity, Grant programs—labor, Migrant labor, Reporting and recordkeeping requirements.

20 CFR Part 655

Administrative practice and procedure, Foreign workers,

Employment, Employment and training, Enforcement, Forest and forest products, Fraud, Health professions, Immigration, Labor, Passports and visas, Penalties, Reporting and recordkeeping requirements, Unemployment, Wages, Working conditions.

20 CFR Part 658

Administrative practice and procedure, Employment, Grant programs—labor, Reporting and recordkeeping requirements.

29 CFR Part 501

Administrative practice and procedure, Agricultural, Aliens, Employment, Housing, Housing standards, Immigration, Labor, Migrant labor, Penalties, Transportation, Wages.

For the reasons stated in the preamble, the Department of Labor proposes to amend 20 CFR parts 651, 653, 655, and 658 and 29 CFR part 501 to read as follows:

Title 20: Employees' Benefits

Employment and Training Administration

PART 653—SERVICES OF THE WAGNER-PEYSER ACT EMPLOYMENT SERVICE SYSTEM

■ 3. The authority citation for part 653 continues to read as follows:

Authority: Secs. 167, 189, 503, Public Law 113–128, 128 Stat. 1425 (Jul. 22, 2014); 29 U.S.C. chapter 4B; 38 U.S.C. part III, chapters 41 and 42.

■ 4. Amend § 653.501 by:

- a. Revising paragraph (b)(4);
- b. Revising paragraph (c)(1)(iv)(E);
- c. Revising paragraphs (c)(3) introductory text, (c)(3)(i) and (iv), and (c)(5); and
- d. Adding paragraphs (d)(4), (7), and (8).

The additions and revisions read as follows:

§ 653.501 Requirements for processing clearance orders.

* * * * *

(b) * * *

(4) Prior to placing a job order into intrastate or interstate clearance, ES staff must consult the Department's Office of Foreign Labor Certification and Wage and Hour Division debarment lists.

(i) If the employer requesting access to the clearance system is currently debarred from participating in the H–2A or H–2B foreign labor certification programs, the SWA must initiate discontinuation of services pursuant to part 658, subpart F, of this chapter.

(ii) If the employer requesting access to the clearance system is currently

discontinued from receiving ES services under § 658.503 of this chapter by the order-holding SWA, the SWA must not approve the clearance order for placement into intrastate or interstate clearance.

(iii) * * *

(c) * * *

(1) * * *

(iv) * * *

(E) The hourly wage rate or the piece rate estimated in hourly wage rate equivalents for each activity and unit size;

* * * * *

(3) * * *

(i) The employer will provide to workers referred through the clearance system the number of hours of work cited in paragraph (c)(1)(iv)(D) of this section for the week beginning with the anticipated date of need, unless the employer has amended the date of need at least 10 business days prior to the original date of need (pursuant to paragraph (c)(3)(iv) of this section) by so notifying the order-holding office in writing (email notification may be acceptable). The SWA must make a record of this notification and must attempt to inform referred workers of the change expeditiously.

* * * * *

(iv) The employer will expeditiously notify the order-holding office or SWA by emailing and telephoning immediately upon learning that a crop is maturing earlier or later, or that weather conditions, over-recruitment or other factors have changed the terms and conditions of employment.

* * * * *

(5) If there is a change to the anticipated date of need and the employer fails to notify the order-holding office at least 10 business days prior to the original date of need the employer must pay eligible (pursuant to paragraph (d)(4) of this section) workers referred through the clearance system the specified hourly rate of pay, or if the pay is piece-rate, the higher of the Federal or State minimum wage for the first week starting with the originally anticipated date of need or provide alternative work if such alternative work is stated on the clearance order. If an employer fails to comply under this section the order holding office may notify the Department's Wage and Hour Division for possible enforcement.

(d) * * *

(4) The applicant holding office must notify all referred farmworkers, farm labor contractors on behalf of farmworkers, or family heads on behalf of farmworker family members, to contact an ES office, preferably the

order-holding office, to verify the date of need cited in the clearance order between 9 and 5 business days prior to the original date of need cited in the clearance order; and that failure to do so will disqualify the referred farmworker from the first weeks' pay as described in paragraph (c)(3)(i) of this section. The SWA must make a record of this notification.

* * * * *

(7) If an order holding office learns that a crop is maturing earlier than expected or that other material factors, including weather conditions and recruitment levels have changed since the date the clearance order was accepted, the SWA must contact immediately the applicant holding office which must inform immediately crews and families scheduled to report to the job site of the changed circumstances and must adjust arrangements on behalf of such crews and families.

(8) When there is a delay in the date of need, SWAs must document notifications by employers and contacts by individual farmworkers or crew leaders on behalf of farmworkers or family heads on behalf of farmworker family members to verify the date of need.

* * * * *

PART 655—TEMPORARY EMPLOYMENT OF FOREIGN WORKERS IN THE UNITED STATES

■ 5. The authority citation for part 655 continues to read as follows:

Section 655.0 issued under 8 U.S.C. 1101(a)(15)(E)(iii), 1101(a)(15)(H)(i) and (ii), 8 U.S.C. 1103(a)(6), 1182(m), (n), and (t), 1184(c), (g), and (j), 1188, and 1288(c) and (d); sec. 3(c)(1), Pub. L. 101–238, 103 Stat. 2099, 2102 (8 U.S.C. 1182 note); sec. 221(a), Pub. L. 101–649, 104 Stat. 4978, 5027 (8 U.S.C. 1184 note); sec. 303(a)(8), Pub. L. 102–232, 105 Stat. 1733, 1748 (8 U.S.C. 1101 note); sec. 323(c), Pub. L. 103–206, 107 Stat. 2428; sec. 412(e), Pub. L. 105–277, 112 Stat. 2681 (8 U.S.C. 1182 note); sec. 2(d), Pub. L. 106–95, 113 Stat. 1312, 1316 (8 U.S.C. 1182 note); 29 U.S.C. 49k; Pub. L. 107–296, 116 Stat. 2135, as amended; Pub. L. 109–423, 120 Stat. 2900; 8 CFR 214.2(h)(4)(i); 8 CFR 214.2(h)(6)(iii); and sec. 6, Pub. L. 115–218, 132 Stat. 1547 (48 U.S.C. 1806).

Subpart A issued under 8 CFR 214.2(h).

Subpart B issued under 8 U.S.C.

1101(a)(15)(H)(ii)(a), 1184(c), and 1188; and 8 CFR 214.2(h).

Subpart E issued under 48 U.S.C. 1806.

Subparts F and G issued under 8 U.S.C. 1288(c) and (d); sec. 323(c), Pub. L. 103–206, 107 Stat. 2428; and 28 U.S.C. 2461 note, Pub. L. 114–74 at section 701.

Subparts H and I issued under 8 U.S.C.

1101(a)(15)(H)(i)(b) and (b)(1), 1182(n), and (t), and 1184(g) and (j); sec. 303(a)(8), Pub. L.

102–232, 105 Stat. 1733, 1748 (8 U.S.C. 1101 note); sec. 412(e), Pub. L. 105–277, 112 Stat. 2681; 8 CFR 214.2(h); and 28 U.S.C. 2461 note, Pub. L. 114–74 at section 701.

Subparts L and M issued under 8 U.S.C. 1101(a)(15)(H)(i)(c) and 1182(m); sec. 2(d), Pub. L. 106–95, 113 Stat. 1312, 1316 (8 U.S.C. 1182 note); Pub. L. 109–423, 120 Stat. 2900; and 8 CFR 214.2(h).

■ 6. Amend § 655.103 by removing definitions for *Key service provider* and *Labor organization*.

■ 8. Amend § 655.120 by revising paragraphs (a) and (b)(2) and (3) to read as follows:

§ 655.120 Offered wage rate.

(a) *Employer obligation*. Except for occupations covered by §§ 655.200 through 655.235, to comply with its obligation under § 655.122(l), an employer must offer, advertise in its recruitment, and pay a wage that is at least the highest of:

(1) The AEWR;

(2) A prevailing wage rate, if the OFLC Administrator has approved a prevailing wage survey for the applicable crop activity or agricultural activity and, if applicable, a distinct work task or tasks performed in that activity, meeting the requirements of paragraph (c) of this section;

(3) The agreed-upon collective bargaining wage;

(4) The Federal minimum wage; or

(5) The State minimum wage.

(b) * * *

(2) The OFLC Administrator will publish, at least once in each calendar year, on a date to be determined by the OFLC Administrator, the AEWRs for each State as a notice in the **Federal Register**.

(3) If an updated AEWR for the occupational classification and geographic area is published in the **Federal Register** during the work contract, and the updated AEWR is higher than the highest of the previous AEWR, a prevailing wage for the crop activity or agricultural activity and, if applicable, a distinct work task or tasks performed in that activity and geographic area, the agreed-upon collective bargaining wage, the Federal minimum wage, or the State minimum wage, the employer must pay at least the updated AEWR upon the effective date of the updated AEWR published in the **Federal Register**.

* * * * *

■ 9. Amend § 655.122 by revising paragraphs (h)(4), (i)(1) (ii), (l), and (n) to read as follows:

§ 655.122 Contents of job offers.

* * * * *

(h) * * *

(4) *Employer-provided transportation.* All employer-provided transportation must comply with all applicable local, State, or Federal laws and regulations, and must provide, at a minimum, the same transportation safety standards, driver licensure, and vehicle insurance as required under 29 U.S.C. 1841, 29 CFR 500.104 or 500.105, and 29 CFR 500.120 through 500.128. The job offer must include a description of the modes of transportation (e.g., type of vehicle) that will be used for inbound, outbound, daily, and any other transportation. If workers' compensation is used to cover transportation in lieu of vehicle insurance, the employer must either ensure that the workers' compensation covers all travel or that vehicle insurance exists to provide coverage for travel not covered by workers' compensation and it must have property damage insurance.

(i) * * *

(1) For purposes of this paragraph (i)(1) a workday means the number of hours in a workday as stated in the job order and excludes the worker's Sabbath and Federal holidays. The employer must offer a total number of hours to ensure the provision of sufficient work to reach the three-fourths guarantee. The work hours must be offered during the work period specified in the work contract, or during any modified work contract period to which the worker and employer have mutually agreed and that has been approved by the CO.

(ii) The work contract period can be shortened by agreement of the parties only with the approval of the CO. In the event the worker begins working later than the specified beginning date of the contract, the guarantee period begins with the first workday after the arrival of the worker at the place of employment, and continues until the last day during which the work contract and all extensions thereof are in effect.

* * * * *

(l) *Rates of pay.* Except for occupations covered by §§ 655.200 through 655.235, the employer must pay the worker at least the AEW; a prevailing wage if the OFLC Administrator has approved a prevailing wage survey for the applicable crop activity or agricultural activity and, if applicable, a distinct work task or tasks performed in that activity, meeting the requirements of § 655.120(c); the agreed-upon collective bargaining rate; the Federal minimum wage; or the State minimum wage rate, whichever is highest, for every hour or portion thereof worked during a pay period.

(1) The offered wage may not be based on commission, bonuses, or other

incentives, unless the employer guarantees a wage paid on a weekly, semi-monthly, or monthly basis that equals or exceeds the AEW, prevailing wage rate, the Federal minimum wage, the State minimum wage, or any agreed-upon collective bargaining rate, whichever is highest; or

(2) If the worker is paid on a piece rate basis and at the end of the pay period the piece rate does not result in average hourly piece rate earnings during the pay period at least equal to the amount the worker would have earned had the worker been paid at the appropriate hourly rate:

(i) The worker's pay must be supplemented at that time so that the worker's earnings are at least as much as the worker would have earned during the pay period if the worker had instead been paid at the appropriate hourly wage rate for each hour worked;

(ii) The piece rate must be no less than the prevailing piece rate for the crop activity or agricultural activity and, if applicable, a distinct work task or tasks performed in that activity in the geographic area if one has been issued by the OFLC Administrator; and

(iii) If the employer who pays by the piece rate requires one or more minimum productivity standards of workers as a condition of job retention, such standards must be specified in the job offer and be no more than those required by the employer in 1977, unless the OFLC Administrator approves a higher minimum, or, if the employer first applied for temporary agricultural labor certification after 1977, such standards must be no more than those normally required (at the time of the first *Application for Temporary Employment Certification*) by other employers for the activity in the area of intended employment.

(3) If applicable, the employer must state in the job order:

(i) That overtime hours may be available;

(ii) The wage rate(s) to be paid for any such overtime hours;

(iii) The circumstances under which the wage rate(s) for overtime hours will be paid, including, but not limited to, after how many hours in a day or workweek the overtime wage rate will be paid, and whether overtime wage rates will vary between places of employment; and

(iv) Where the overtime pay is required by law, the applicable Federal, State, or local law requiring the overtime pay.

* * * * *

(n) *Abandonment of employment or termination for cause.* If a worker

voluntarily abandons employment before the end of the contract period, or is terminated for cause, and the employer notifies the NPC, and DHS in the case of an H-2A worker, in writing or by any other method specified by the Department in a notice published in the **Federal Register** or specified by DHS not later than 2 working days after such abandonment occurs, the employer will not be responsible for providing or paying for the subsequent transportation and subsistence expenses of that worker under this section, and that worker is not entitled to the three-fourths guarantee described in paragraph (i) of this section, and, in the case of a U.S. worker, the employer will not be obligated to contact that worker under § 655.153. Abandonment will be deemed to begin after a worker fails to report to work at the regularly scheduled time for 5 consecutive working days without the consent of the employer. The employer is required to maintain records of such notification to the NPC, and DHS in the case of an H-2A worker, for not less than 3 years from the date of the certification.

■ 10. Amend § 655.130 by revising paragraphs (a) and removing paragraphs (a)(1), (a)(2), (a)(3), and (a)(4), to read as follows:

§ 655.130. Application filing requirements

(a) *What to file.* An employer that desires to apply for temporary agricultural labor certification of one or more nonimmigrant workers must file a completed *Application for Temporary Employment Certification*, all supporting documentation and information required at the time of filing under §§ 655.131 through 655.135, and, unless a specific exemption applies, a copy of Form ETA-790/790A, submitted as set forth in § 655.121(a). The *Application for Temporary Employment Certification* must include a valid FEIN as well as a valid place of business (physical location) in the United States and a means by which it may be contacted for employment.

■ 11. Amend § 655.132 by revising paragraph (e)(1) to read as follows:

§ 655.132 H-2A labor contractor filing requirements.

* * * * *

(e) * * *

(1) All housing used by workers and owned, operated, or secured by the fixed-site agricultural business complies with the applicable standards as set forth in § 655.122(d) and certified by the SWA; and

* * * * *

■ 12. Amend § 655.135 by:
■ a. Revising paragraph (h);

- b. Deleting subsections (m), (n), and (p); and
- c. Renumbering subsection (o) to (m).
The revision reads as follows:

§ 655.135 Assurance and obligations of H-2A employers.

* * * * *

(h) * * *

(1) Filed a complaint under or related to 8 U.S.C. 1188 or this subpart or any Department regulation in this chapter or 29 CFR part 501 promulgated under 8 U.S.C. 1188;

(2) Instituted or caused to be instituted any proceeding under or related to 8 U.S.C. 1188 or this subpart or any Department regulation in this chapter or 29 CFR part 501 promulgated under 8 U.S.C. 1188;

(3) Testified or is about to testify in any proceeding under or related to 8 U.S.C. 1188 or this subpart or any Department regulation in this chapter or 29 CFR part 501 promulgated under 8 U.S.C. 1188;

(4) Consulted with an employee of a legal assistance program or an attorney on matters related to 8 U.S.C. 1188 or this subpart or any Department regulation in this chapter or 29 CFR part 501 promulgated under 8 U.S.C. 1188; or

(5) Exercised or asserted on behalf of themselves or others any right or protection afforded by 8 U.S.C. 1188 or this subpart or any Department regulation in this chapter or 29 CFR part 501 promulgated under 8 U.S.C. 1188.

* * * * *

(m) *Passport withholding.* During the period of employment that is the subject of the Application for Temporary Labor Certification, the employer may not hold or confiscate a worker's passport, visa, or other immigration or government identification document except where the worker states in writing that: the worker voluntarily requested that the employer keep these documents safe, the employer did not direct the worker to submit such a request, and the worker understands that the passport, visa, or other immigration or government identification document will be returned to the worker immediately upon the worker's request.

* * * * *

- 13. Remove § 655.137.

§ 655.137 [Removed]

- 14. Amend § 655.145 by revising the section title and paragraph (b) to read as follows:

§ 655.145 Amendments to Applications for Temporary Employment Certification.

* * * * *

(b) *Minor changes to the period of employment.* The *Application for Temporary Employment Certification* may be amended to make minor changes in the total period of employment. Changes will not be effective until submitted in writing and approved by the CO. In considering whether to approve the request, the CO will review the reason(s) for the request, determine whether the reason(s) are on the whole justified, and take into account the effect any change(s) would have on the adequacy of the underlying test of the domestic labor market for the job opportunity. An employer must demonstrate that the change to the period of employment could not have been foreseen, and the crops or commodities will be in jeopardy prior to the expiration of an additional recruitment period. If the request is for a delay in the first date of need and is made after workers have departed for the employer's place of employment, the CO may only approve the change if the employer includes with the request a written assurance signed and dated by the employer that all workers who are already traveling to the place of employment will be provided housing and subsistence, without cost to the workers, until work commences. Upon acceptance of an amendment, the CO will submit to the SWA any necessary modification to the job order.

- 15. Amend § 655.167 by removing paragraphs (c)(8), (c)(9), (c)(10), (c)(11), and (c)(12).

- 16. Remove § 655.175.

§ 655.175 [Removed]

- 17. Amend § 655.210 by revising paragraph (g) to read as follows:

§ 655.210 Contents of herding and range livestock job orders.

* * * * *

(g) *Rates of pay.* The employer must pay the worker at least the monthly AEWR, as specified in § 655.211, the agreed-upon collective bargaining wage, or the applicable minimum wage imposed by Federal or State law or judicial action, in effect at the time work is performed, whichever is highest, for every month of the job order period or portion thereof.

(1) The offered wage shall not be based on commissions, bonuses, or other incentives, unless the employer guarantees a wage that equals or exceeds the monthly AEWR, the agreed-upon collective bargaining wage, or the applicable minimum wage imposed by Federal or State law or judicial action, or any agreed-upon collective bargaining rate, whichever is highest, and must be paid to each worker free

and clear without any unauthorized deductions.

(2) The employer may prorate the wage for the initial and final pay periods of the job order period if its pay period does not match the beginning or ending dates of the job order. The employer also may prorate the wage if a worker is voluntarily unavailable to work for personal reasons.

(3) If applicable, the employer must state in the job order:

(i) That overtime hours may be available;

(ii) The wage rate(s) to be paid for any such overtime hours;

(iii) The circumstances under which the wage rate(s) for overtime hours will be paid, including, but not limited to, after how many hours in a day or workweek the overtime wage rate will be paid, and whether overtime wage rates will vary between-place(s) of employment; and

(iv) Where the overtime pay is required by law, the applicable Federal, State, or local law requiring the overtime pay.

* * * * *

- 18. Amend § 655.211 by revising paragraph (a) to read as follows:

§ 655.211 Herding and range livestock wage rate.

(a) *Compliance with rates of pay.*

(1) To comply with its obligation under § 655.210(g), an employer must offer, advertise in its recruitment, and pay each worker employed under §§ 655.200 through 655.235 a wage that is at least the highest of the monthly AEWR established under this section, the agreed-upon collective bargaining wage, or the applicable minimum wage imposed by Federal or State law or judicial action.

(2) If the monthly AEWR established under this section is adjusted during a work contract, and is higher than both the agreed-upon collective bargaining wage and the applicable minimum wage imposed by Federal or State law or judicial action in effect at the time the work is performed, the employer must pay at least that adjusted monthly AEWR upon the effective date of the updated monthly AEWR published by the Department in the **Federal Register**.

* * * * *

PART 658—ADMINISTRATIVE PROVISIONS GOVERNING THE WAGNER-PEYSER ACT EMPLOYMENT SERVICE

The authority citation for part 658 continues to read as follows:

Authority: Secs. 189, 503, Pub. L. 113–128, 128 Stat. 1425 (Jul. 22, 2014); 29 U.S.C. chapter 4B.

■ 19. Amend § 658.502 by revising or adding the following paragraphs to provide an opportunity for the employer to request a hearing:

- a. Revising paragraphs (a)(1)(ii) and (iii), and adding paragraph (a)(1)(iv);
- b. Revising paragraphs (a)(2)(i) and (ii), and adding paragraph (a)(2)(iii);
- c. Revising paragraphs (a)(3)(ii) and (iii), and adding paragraph (a)(3)(iv);
- d. Revising paragraphs (a)(5)(iii) and adding paragraph (a)(5)(iv);
- e. Revising paragraph (a)(6)(vi) and adding paragraph (a)(6)(vii);
- f. Revising paragraphs (a)(7)(iii) and adding paragraph (a)(7)(iv);
- g. Revising paragraph (a)(8);
- h. Revising paragraph (b);
- i. Adding paragraphs (c) and (d).

The additions and revisions read as follows:

§ 658.502 Notification to employers of intent to discontinue services

(a) * * *

(1) * * *

(ii) Withdraws the terms and conditions and resubmits the job order in compliance with all employment-related laws;

(iii) If the job is no longer available, makes assurances that all future job orders submitted will be in compliance with all employment-related laws; or

(iv) Requests a hearing from the SWA pursuant to § 658.417.

(2) * * *

(i) Resubmits the order with the required assurances;

(ii) If the job is no longer available, makes assurances that all future job orders submitted will contain all assurances required pursuant to the Agricultural Recruitment System for U.S. Workers at part 653, subpart F, of this chapter; or

(ii) Requests a hearing from the SWA pursuant to § 658.417.

(3) * * *

(ii) Provides adequate evidence that there was full compliance with the assurances made on the job orders;

(iii) Provides adequate evidence that it has resolved the misrepresentation of terms and conditions of employment or noncompliance with assurances and provides adequate assurance that specifications on future orders will accurately represent the terms and conditions of employment and that there will be full compliance with all job order assurances; or

(iv) Requests a hearing from the SWA pursuant to § 658.417.

* * * * *

(5) * * *

(iii) Provides assurances that any policies, procedures, or conditions responsible for the violation have been

corrected and the same or similar violations are not likely to occur in the future; or

(iv) Requests a hearing from the SWA pursuant to § 658.417.

(6) * * *

(vi) Provides assurances that qualified workers referred in the future will be accepted or, if the time period described in § 655.135(d) of this chapter has lapsed, provides assurances that qualified workers referred on all future criteria clearance orders will be accepted; or

(vii) Requests a hearing from the SWA pursuant to § 658.417.

(7) * * *

(iii) Provides assurances that it will cooperate in future field checks; or

(iv) Requests a hearing from the SWA pursuant to § 658.417.

(8) Where the decision is based on § 658.501(a)(8), the SWA must list and provide basic facts explaining the prior instances where the employer has repeatedly caused initiation of discontinuation proceedings. The SWA must notify the employer that all ES services will be terminated unless the employer within 20 working days provides adequate evidence that the SWA's initiation of discontinuation in prior proceedings was unfounded or the employer requests a hearing from the SWA pursuant to § 658.417.

(b) SWA officials must discontinue services immediately in accordance with § 658.503, without providing the notice described in this section, if an employer has met any of the bases for discontinuation of services under § 658.501(a) and, in the judgment of the State Administrator, exhaustion of the administrative procedures set forth in this section would cause substantial harm to a significant number of workers.

(c) If the employer chooses to respond pursuant to this section by providing documentary evidence or assurances, it must at the same time request a hearing if such hearing is desired in the event that the SWA does not accept the documentary evidence or assurances as adequate.

(d) If the employer makes a timely request for a hearing, in accordance with this section, the SWA must follow procedures set forth at § 658.411 and notify the complainant whenever the discontinuation of services is based on a complaint pursuant to § 658.411.

■ 20. Amend § 658.503 by:

- a. Revising paragraph (a) to align with changes made in § 658.502 that provide the employer an opportunity to request a hearing in response the SWA's notice of its intent to discontinue ES services, reverting to the prior process that the discontinuation is effective as of the

date of the SWA's notice, and to remove the requirement for the SWA to notify OWI of final determinations to discontinue ES services;

■ b. Revising paragraph (b) to align with changes made in § 658.502 that provide the employer an opportunity to request a hearing in response the SWA's notice of its intent to discontinue ES services and to remove the requirement for the SWA to notify OWI of final determinations to discontinue ES services;

■ c. Revising paragraph (e) so that the effect of the discontinuation only applies to the SWA that issued the discontinuation of ES services;

The additions and revisions read as follows:

§ 658.503 Discontinuation of services.

(a) Within 20 working days of receipt of the employer's response to the SWA's notification under § 658.502(a), or at least 20 working days after the SWA's notification has been received by the employer if the SWA does not receive a response, the SWA must notify the employer in writing of its final determination. If the SWA determines that the employer did not provide a satisfactory response in accordance with § 658.502(a), or the employer has not requested a hearing, the SWA must immediately terminate services to the employer. The SWA's notification must specify the reasons for its determination and state that the discontinuation of services is effective as of the date of the notification and that the employer may request reinstatement of ES services as described in § 658.504.

(b) Where the SWA discontinues services immediately under § 658.502(b), the SWA's written notification must specify the facts supporting the applicable basis for discontinuation under § 658.501(a), the reasons that exhaustion of the administrative procedures would cause substantial harm to workers, and that services are discontinued as of the date of the notification. The notification must also state that the employer may request reinstatement or appeal the determination by requesting a hearing pursuant to § 658.504, and that a request for a hearing relating to immediate discontinuation does not stay the discontinuation pending the outcome of the hearing.

(c) * * *

(d) * * *

(e) If the SWA discontinues services to an employer, the employer cannot participate in or receive Wagner-Peyser Act ES Services provided by the SWA to employers pursuant to parts 652 and 653 of this chapter. From the date of

discontinuance, the SWA that issued the determination must remove the employer's active job orders from its clearance system and may not process any future job orders from the employer or provide any other services pursuant to parts 652 and 653 of this chapter to the employer unless services have been reinstated under § 658.504.

(f) * * *

■ 21. Amend § 658.504 by:

■ a. Revising paragraph (a) to align with changes made in § 658.502 that provide the employer an opportunity to request a hearing in response to the SWA's notice of its intent to discontinue services;

■ b. Revising paragraphs (c) and revising paragraph (d) so that the requirement for the SWA to reinstate services if ordered by an appropriate authority may occur outside of the hearing process, consistent with the prior regulatory text;

■ c. Revising paragraph (d) to remove the requirement for the SWA to notify OWI of final determinations to discontinue ES services;

The additions and revisions read as follows:

§ 658.504 Reinstatement of services.

(a) Where the SWA discontinues services to an employer under § 658.502(b) or § 658.503, the employer may submit a written request for reinstatement of services to the SWA.

* * * * *

(c) If the employer makes a timely request for a hearing, the SWA must follow the procedures set forth at § 658.417.

(d) The SWA must reinstate services to an employer if ordered to do so by a State hearing official, Regional Administrator, or Federal ALJ.

PART 501—ENFORCEMENT OF CONTRACTUAL OBLIGATIONS FOR TEMPORARY ALIEN AGRICULTURAL WORKERS ADMITTED UNDER SECTION 218 OF THE IMMIGRATION AND NATIONALITY ACT

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

Authority: 8 U.S.C. 1101(a)(15)(H)(ii)(a), 1184(c), and 1188; 28 U.S.C. 2461 note; and sec. 701, Pub. L. 114–74, 129 Stat. 584.

■ 23. Amend § 501.3(a) by removing the definitions of *Key service provider* and *Labor organization*.

■ 24. Amend § 501.4 by revising paragraph (a) to read as follows:

§ 501.4 Discrimination prohibited.

(a) A person may not intimidate, threaten, restrain, coerce, blacklist, discharge, or in any manner discriminate against any person who has:

(1) Filed a complaint under or related to 8 U.S.C. 1188 or this part;

(2) Instituted or causes to be instituted any proceedings related to 8 U.S.C. 1188, 20 CFR part 655, subpart B, or this part;

(3) Testified or is about to testify in any proceeding under or related to 8 U.S.C. 1188, 20 CFR part 655, subpart B, or this part;

(4) Consulted with an employee of a legal assistance program or an attorney on matters related to 8 U.S.C. 1188, 20 CFR part 655, subpart B, or this part; or

(5) Exercised or asserted on behalf of themselves or others any right or protection afforded by 8 U.S.C. 1188, 20 CFR part 655, subpart B, or this part.

(b) * * *

Signed this 27th day of June, 2025.

Susan Frazier,

Acting Assistant Secretary, Employment and Training Administration.

Signed this 27th day of June, 2025.

Donald Harrison,

Acting Administrator, Wage and Hour Division.

[FR Doc. 2025–12315 Filed 6–30–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–125710–18]

RIN 1545–BP07

Regulations Under Section 382(h) Related to Built-In Gain and Loss; Withdrawal

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Withdrawal of notices of proposed rulemaking.

SUMMARY: This document withdraws two notices of proposed rulemaking containing proposed regulations on the treatment of built-in items of income, gain, deduction, and loss taken into account by a loss corporation after an ownership change. The proposed regulations would have affected corporations that experience an ownership change under section 382(h) of the Internal Revenue Code (Code).

DATES: As of July 2, 2025, the notices of proposed rulemaking that were published in the **Federal Register** on September 10, 2019 (84 FR 47455), and January 14, 2020 (85 FR 2061), are withdrawn.

ADDRESSES: Send paper submissions to CC:PA:01:PR (REG–125710–18), Room

5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Lilia D. Stamm at (202) 317–3598 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On September 10, 2019, the Department of the Treasury (Treasury Department) and the IRS published a notice of proposed rulemaking (REG–125710–18) in the **Federal Register** (84 FR 47455) under section 382(h) (2019 proposed regulations) that would have modified §§ 1.382–2 and 1.382–7 of the Income Tax Regulations (26 CFR part 1). On January 14, 2020, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–125710–18) in the **Federal Register** (85 FR 2061) under section 382(h) (2020 proposed regulations) that modified certain provisions in the 2019 proposed regulations.

The 2019 proposed regulations would have adopted as mandatory, with certain modifications, (i) the safe harbor net unrealized built-in gain (NUBIG) and net unrealized built-in loss (NUBIL) computation provided in Notice 2003–65, 2003–40 I.R.B. 747, based on the principles of section 1374 of the Code, and (ii) the “1374 approach” (as described in Notice 2003–65) with respect to the identification of recognized built-in gain (RBIG) and recognized built-in loss (RBIL).

The 2019 proposed regulations would have modified the rules in §§ 1.382–2 and 1.382–7: (i) to eliminate the treatment of depreciation deductions on certain built-in gain assets as RBIG, in the absence of actual gain or income recognized by the loss corporation; (ii) to exclude adequately secured nonrecourse liabilities and all recourse liabilities from the initial NUBIG/NUBIL calculation, and treat post-change cancellation-of-indebtedness income as RBIG only in certain circumstances; (iii) to introduce a “consistency rule” in order to exclude certain change-date items allocated to the pre-change period (as defined in § 1.382–6(g)(2)) from the calculation of NUBIG and NUBIL; (iv) to exclude prepaid income as an item of RBIG; (v) to exclude dividends paid on stock during the recognition period (as defined in section 382(h)(7)) as RBIG; and (vi) to exclude section 382 disallowed business interest carryforwards (as defined in § 1.382–2(a)(7)) as items of RBIL under section 382(h)(6)(B).

The 2019 proposed regulations reflected the view that the certainty

provided by the 1374 approach would streamline the calculation of built-in gains and built-in losses for taxpayers and the administration of section 382(h) for the IRS. In developing the 2019 proposed regulations, the Treasury Department and the IRS also considered the “338 approach” (as described in Notice 2003–65) to be more complex than the 1374 approach and to result in overstatements of RBIG and RBIL.

The Treasury Department and the IRS received several comments in response to the 2019 proposed regulations, many of which were critical of the foregoing view. In response to the comments received, the Treasury Department and the IRS are withdrawing the 2019 proposed regulations and the 2020 proposed regulations.

The Treasury Department and the IRS are continuing to study the issues addressed in the 2019 proposed regulations and expect to issue a revised notice of proposed rulemaking regarding such issues. By the terms of Notice 2003–65, taxpayers may continue to rely on the approaches set forth therein for purposes of applying section 382(h) to an ownership change that occurs prior to the effective date of temporary or final regulations under section 382(h). See Notice 2003–65, Part V.

Drafting Information

The principal author of this notice is Brian R. Loss of the Office of Associate Chief Counsel (Corporate). However, other personnel from the Treasury Department and the IRS participated in its development.

List of Subjects in 26 CFR Part 1

Income Taxes, Reporting and recordkeeping requirements.

Withdrawal of Proposed Amendments to the Regulations

Under the authority of 26 U.S.C. 7805, the notices of proposed rulemaking (REG–125710–18) that were published in the **Federal Register** on September 10, 2019 (84 FR 47455), and January 14, 2020 (85 FR 2061), are withdrawn.

Edward T. Killen,

Acting Chief Tax Compliance Officer.

[FR Doc. 2025–12193 Filed 7–1–25; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

Employment and Training Administration

29 CFR Parts 29 and 30

[Docket No. ETA–2025–0006]

RIN 1205–AC21

Prohibiting Illegal Discrimination in Registered Apprenticeship Programs

AGENCY: Employment and Training Administration, Labor.

ACTION: Proposed rule, request for comments.

SUMMARY: The Department of Labor (DOL or the Department) is issuing this notice of proposed rulemaking (NPRM) to remove undue regulatory burdens on registered apprenticeship program sponsors. The Department’s proposal would rescind certain regulatory provisions that it believes are unlawful. It also includes conforming, technical changes to the Department’s regulation that addresses Labor Standards for the Registration of Apprenticeship Programs. This proposed rule would streamline and simplify sponsors’ obligations, while maintaining broad and effective nondiscrimination protections for apprentices and those seeking entry into apprenticeship programs. A brief summary of this document may be found at [regulations.gov](https://www.regulations.gov) by searching by the RIN 1205–AC21.

DATES: Interested persons are invited to submit written comments on the proposed rule on or before September 2, 2025.

ADDRESSES: You may send comments, identified by Docket No. ETA–2025–0006 and Regulatory Identification Number (RIN) 1205–AC21, by any of the following methods:

Federal Rulemaking Portal: <https://www.regulations.gov>. Search for the above-referenced RIN, open the proposed rule, and follow the on-screen instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking or “RIN 1205–AC21.”

Please be advised that the Department will post comments received that relate to this proposed rule to <https://www.regulations.gov>, including any personal information provided. The <https://www.regulations.gov> website is the Federal e-Rulemaking Portal and all comments posted there are available and accessible to the public. Please do not submit comments containing trade secrets, confidential or proprietary

commercial or financial information, personal health information, sensitive personally identifiable information (for example, social security numbers, driver’s license or state identification numbers, passport numbers, or financial account numbers), or other information that you do not want to be made available to the public. Should the agency become aware of such information, the agency reserves the right to redact or refrain from posting sensitive information, libelous, or otherwise inappropriate comments, including those that contain obscene, indecent, or profane language; that contain threats or defamatory statements; or that contain hate speech. Please note that depending on how information is submitted, the agency may not be able to redact the information and instead reserves the right to refrain from posting the information or comment in such situations.

Docket: For access to the docket to read background documents, comments received, or the plain-language summary of the proposed rule of not more than 100 words in length required by the Providing Accountability Through Transparency Act of 2023, go to <https://www.regulations.gov> (search using RIN 1205–AC21 or Docket No. ETA–2025–0006). If you need assistance to review the comments, contact the Office of Policy Development and Research at 202–693–3700 (this is not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Luke Murren, Acting Administrator, Office of Policy Development and Research, U.S. Department of Labor, Employment and Training Administration, 200 Constitution Avenue NW, Room N–5641, Washington, DC 20210, Telephone: 202–693–3700 (voice) (this is not a toll-free number). For persons with a hearing or speech disability who need assistance using the telephone system, please dial 711 to access telecommunications relay services.

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I. Background

A. Registered Apprenticeship

For nearly a century, registered apprenticeship has stood as a foundational, employer-led model of workforce development anchored in private sector leadership and real-world skill development that accelerates the recruitment, training, and retention of highly proficient workers in the skilled occupations employers need. This training model supports the development of high quality, skilled workers without the high cost or inefficiencies often associated with traditional academic pathways. Registered apprenticeship offers a high-quality, industry-driven career pathway in which employers can develop and prepare their future workforce, and individuals can obtain paid work experience with a mentor and receive progressive wage increases; classroom instruction; and a portable, nationally recognized credential. Registered apprenticeship programs are industry-vetted and are approved and validated by DOL or a State Apprenticeship Agency (SAA).

Employers and industry stakeholders continuously refine the registered apprenticeship model to meet the changing workforce system demands and emerging skills needs. Apprentices gain affordable, hands-on training while earning wages and receiving guidance from qualified journeyworkers. Program sponsors use registered apprenticeship to build a skilled, job-ready workforce that enhances their competitiveness and yields strong returns on investment. According to the Common Reporting Information System, individuals who complete registered apprenticeship programs earn an average annual salary of approximately \$84,000, exceeding the average earnings of associate degree

holders, which range from \$50,000 to \$56,000 per year.¹ Employers also report positive outcomes resulting from their participation in registered apprenticeship; for example, an Abt Associates report that surveyed employers who participate in registered apprenticeship found that registered apprenticeship programs delivered a return on investment of 44 percent, reduce staff turnover, boost productivity, and strengthen the talent pipeline.²

Registered apprenticeship programs also yield a 90 percent employment retention rate, indicating that most graduates remain in the workforce after completing their training.³ Over the course of their careers, registered apprenticeship completers earn more than \$300,000 (including benefits) above what their non-apprentice peers earn on average, highlighting the long-term economic advantage of this training model.⁴

Registered apprenticeship programs are voluntarily sponsored by a wide range of organizations, including employers of all sizes—among them Federal, State, and local governments, employers groups, associations, joint labor-management organizations, workforce intermediaries, and educational institutions. Together, these stakeholders comprise the National Apprenticeship System, a voluntary network of registered apprenticeship programs and their sponsors, SAAs, and industry leaders who design apprenticeship training to meet their workforce needs.⁵

On April 23, 2025, President Trump issued Executive Order (E.O.) 14278, *Preparing Americans for High-Paying Skilled Trade Jobs of the Future*, directing the Secretaries of Labor, Education, and Commerce to strengthen the nation's workforce development system. The E.O. affirms the Administration's commitment to

expanding access to high-quality, skills-based career pathways aligned with emerging labor market demands and national economic priorities, including the nationwide goal of reaching and surpassing one million active apprentices. E.O. 14278 positions registered apprenticeship as a key workforce development strategy by promoting expansion into “new industries and occupations, including high-growth and emerging sectors” and by enhancing alignment with career and technical education.

As of Fiscal Year (FY) 2025, the registered apprenticeship system supports 678,014 active apprentices nationwide. This represents an 88.45% increase in participation since FY 2015. The data reflects sustained long-term growth in registered apprenticeship participation across industries and geographies, with Texas and Ohio among the leading states by apprentice volume. The data shows that registered apprenticeship programs are scalable, and an effective workforce development model aligned with both industry demand and national economic goals.⁶

Despite the growth it has achieved over the past decade, registered apprenticeship remains an underutilized approach for developing the skills of America's workforce. In the United States, the proportion of workers who have participated in registered apprenticeship programs constitutes approximately 0.2 percent of the labor force; this is a significantly lower figure than the percentage of apprentices in the labor force seen in several other nations with highly developed apprenticeship systems, including Canada (2.2 percent), Britain (2.7 percent), Australia (3.7 percent), and Germany (3.7 percent).⁷ The Department is currently seeking ways to promote greater uptake of registered apprenticeship in the United States, including removing unnecessary administrative barriers to the registration of new apprenticeship programs that have inhibited the accelerated adoption of this proven workforce development model. Broader adoption of registered apprenticeship by employers across industries and occupations will be necessary to achieve the Administration's goal of one million

¹ U.S. Department of Labor Employment and Training Administration/Kansas Department of Commerce, Common Reporting Information System (CRIS), FY2025 Q1 publication, retrieved Feb. 7, 2025.

² Daniel Kuehn, Sonia M. De La Rosa, Robert I. Lerman, and Kevin Hollenbeck, Abt Associates and Urban Institute, “Do Employers Earn Positive Returns to Investments in Apprenticeship? Evidence from Registered Programs under the American Apprenticeship Initiative,” 2022, https://www.dol.gov/sites/dolgov/files/OASP/evaluation/pdf/AAI/AAI_ROI_Final_Report_508_9-2022.pdf.

³ CRIS, FY2025 Q1 publication, *supra* note 1.

⁴ Kevin Hollenbeck, Mathematica Policy Research, “An Effectiveness Assessment and Cost-Benefit Analysis of Registered Apprenticeship in 10 States,” 2012.

⁵ In registered apprenticeship programs, such training plans are referred to as “work process schedules.”

⁶ U.S. Department of Labor, “Apprentices by State Dashboard,” <https://www.apprenticeship.gov/data-and-statistics/apprentices-by-state-dashboard>, last visited June 27, 2025.

⁷ Robert I. Lerman, Brookings Institution, “Expanding Apprenticeship Opportunities in the United States,” 2014, 3, https://www.hamiltonproject.org/assets/legacy/files/downloads_and_links/expand_apprenticeship_opportunities_united_states_lerman.pdf.

active apprentices. More importantly, widespread adoption of the registered apprenticeship model will ensure that more American workers possess the occupational skills and competencies that employers require to drive innovation and economic expansion.

B. Regulatory History of the 29 CFR Part 30 Regulation

The National Apprenticeship Act of 1937 (NAA) authorizes the Department to formulate and promote labor standards necessary to safeguard the welfare of apprentices.⁸ Within the Department, this responsibility falls to the Employment and Training Administration's (ETA) Office of Apprenticeship (OA). OA registers apprenticeship programs that meet the regulatory requirements set forth in the Code of Federal Regulations (CFR) at 29 CFR parts 29 and 30. The original version of the regulation at 29 CFR part 29 (part 29), titled "Labor Standards of Apprenticeship," was issued in 1977, and amended in 2008. Part 29 implements the NAA by establishing minimum labor standards necessary to safeguard the welfare of apprentices. These include: policies and procedures for the registration, cancellation, and deregistration of apprenticeship programs; safety requirements; progressive wage standards; apprentice-to-journeyworker ratios; apprenticeship agreement content; and the criteria for the recognizing SAAs as Registration Agencies.⁹

The first version of the regulation at 29 CFR part 30 (part 30), titled "Nondiscrimination in Apprenticeship and Training," was published in December of 1963,¹⁰ more than six months before President Lyndon B. Johnson signed the Civil Rights Act into law in July of 1964. Title VII of the Civil Rights Act contains landmark protections for workers against employment discrimination, and its protections extend to apprentices.¹¹ The

1963 version of the Department's part 30 regulation prohibited discrimination based on race, creed, color, or national origin in all phases of a registered apprenticeship program. In the preamble of the NPRM that preceded the publication of the 1963 version of the part 30 final rule, the Department declared that "discrimination based on race, creed, color, or national origin has no place in American life today, particularly in the programs by which young people acquire the skills that determine their future employment prospects," (see 28 FR 11313).

In 1971, the Department revised part 30, renaming it *Equal Employment Opportunity in Apprenticeship and Training*. The 1971 amendments to the regulation prohibited program sponsors from discriminating against apprentices on the basis of sex and religion (thus bringing the regulation into alignment with Title VII of the Civil Rights Act of 1964) and introduced a new requirement for apprenticeship programs with five or more apprentices to establish a written affirmative action program (AAP).¹² The 1971 revision also clarified that such AAPs must include female apprentices.

In 2016, the Department again revised the content of part 30 by expanding the scope of protected characteristics covered by the nondiscrimination provision of the regulation to include, among other things, age, disability, and genetic information. The 2016 version of the part 30 regulation¹³ (2016 final rule) also subjected apprenticeship program sponsors to an expanded set of administratively burdensome requirements, such as: mandating that sponsors provide anti-harassment training to apprentices and to all personnel connected with the administration of their apprenticeship program; imposing a highly complex scheme of demographic and utilization analyses on sponsors to determine whether apprenticeship programs with five or more apprentices were meeting their respective AAP goals; and requiring program sponsors subject to

the AAP provision of the regulation to review their personnel practices on an annual basis to determine their continuing compliance with the foregoing requirements.

The 2016 final rule imposed excessive administrative requirements—as well as affirmative action obligations that are legally vulnerable (which are described in greater detail below)—upon apprenticeship program sponsors. In the Department's view, the imposition of such onerous and burdensome regulatory mandates on sponsors impede the goal of apprenticeship expansion. Such governmental overreach can serve to undermine the establishment, development, and expansion of innovative, high-quality apprenticeship programs. At a time when the rapid expansion of high-quality apprenticeship training is urgently needed to equip Americans of all backgrounds with the occupational skills they need to succeed in a competitive global marketplace, it is imperative that the Department revise and rescind outdated, burdensome, and legally vulnerable regulatory provisions that prevent the accelerated expansion of registered apprenticeship. The Department invites public comments from all interested parties on this proposal to significantly revise the part 30 regulation. The Department is particularly interested in comments from registered apprenticeship stakeholders about any reliance interests that may be impacted by this proposed rule.

C. Need for the Rulemaking

The Department has determined that revising part 30 is necessary to remove regulatory requirements that impose unnecessary administrative burdens on registered apprenticeship program sponsors and hinder the continued growth of this successful workforce development model. In addition to advancing the Department's broader goal of expanding registered apprenticeship, the proposed changes are intended to bring the regulation into alignment with nondiscrimination law. These revisions would eliminate a duplicative and outdated equal employment opportunity framework that applies only to registered apprenticeship and would instead adopt a streamlined approach consistent with the Administration's directive to reduce regulatory burdens. By simplifying compliance obligations and focusing on core legal protections, the Department anticipates that this proposed deregulatory action will support broader program participation and expand

⁸ 29 U.S.C. 50.

⁹ 73 FR 64402. These regulations can be accessed on OA's website at <http://www.doleta.gov/oa/pdf/FinalRule29CFRPart29.pdf>.

¹⁰ The Department's promulgation of the original part 30 regulation was set in motion by the issuance of a statement by President John F. Kennedy on June 4, 1963, that directed the Secretary of Labor, in the conduct of his duties under the National Apprenticeship Act of 1937, "to require that the admission of young workers to apprenticeship programs be on a completely nondiscriminatory basis." Office of the Federal Register, National Archives and Records Service, Public Papers of President John F. Kennedy, "Statement of the President on Equal Employment Opportunity in Federal Apprenticeship and Construction Programs," 1963, 439.

¹¹ Specifically, title VII of the Civil Rights Act of 1964 and its subsequent amendments protect

employees, applicants, and training or apprenticeship program participants from discrimination on the basis of race, color, religion, sex, and national origin. 42 U.S.C. 2000e-2(a); 42 U.S.C. 2000e-3(a); 42 U.S.C. 2000e-2(d). Among other things, title VII bars discrimination against applicants or employees in hiring, firing, compensation, or any term, condition, or privilege of employment. 42 U.S.C. 2000e-2(a)(1). Under title VII, an employer initiative, policy, program, or practice may be unlawful if it involves an employer or other covered entity taking an employment action motivated—in whole or in part—by race, sex, or another protected characteristic. See 42 U.S.C. 2000e-2(m).

¹² 36 FR 6810 (Apr. 8, 1971).

¹³ 81 FR 92026 (Dec. 19, 2016).

registered apprenticeship opportunities for all Americans.

Recent U.S. Supreme Court decisions have clarified the legal limitations on race- and sex-conscious measures under the Equal Protection Clause and Federal civil rights laws. These developments raise serious questions about the validity of certain affirmative action-related provisions in part 30, particularly those that incentivize or induce sponsors to make decisions based on protected characteristics. In light of recent court decisions, the Department has determined that revising part 30 is necessary to ensure the regulatory framework for registered apprenticeship is fully aligned with nondiscrimination standards and legal precedent.¹⁴

Part 30 was last revised in 2016 and contained an expanded range of nondiscrimination and affirmative action requirements for registered apprenticeship program sponsors. The prescriptive affirmative action planning and recordkeeping requirements, among others, have proven burdensome, duplicative, and—following recent legal decisions—potentially unlawful. For example, the protected characteristics contained in § 30.3(a) of the current part 30 rule are duplicative of the nondiscrimination requirements contained in a number of Federal civil rights statutes, including Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act (ADA), and the Age Discrimination in Employment Act (ADEA). In addition, the Department believes that the affirmative action requirements found throughout the existing part 30 regulation conflict with merit principles, may potentially induce the illegal selection of apprentices based on race and sex, and likely will no longer withstand legal scrutiny.

This rulemaking would streamline the part 30 regulation to reduce administrative complexity and compliance burdens, especially for small and mid-sized employers, while preserving core protections against unlawful discrimination. The Department has determined that part 30, as currently structured, is overly prescriptive and unnecessarily restrictive, characteristics which impede

the diversification of industries within the registered apprenticeship ecosystem and are not necessary to safeguard the welfare of apprentices. The Department believes that establishing a clear and concise requirement to comply with all Federal and State laws and regulations prohibiting discrimination aligns more closely with the Department's fundamental statutory mandate to safeguard the welfare of apprentices under the NAA.

Finally, the proposed revision to the part 30 regulation would align with and effectuate the directives contained in recent Executive Orders issued by the current Administration. E.O. 14278, *Preparing Americans for High-Paying Skilled Trade Jobs of the Future* (90 FR 1525, April 28, 2025), directs Federal agencies to identify barriers that prevent the acceleration of the workforce system, including the expansion of registered apprenticeship. Additionally, E.O. 14173, *Ending Illegal Discrimination and Restoring Merit-Based Opportunity* (90 FR 8633, Jan. 31, 2025), directs Federal agencies to “terminate all discriminatory and illegal preferences, mandates, policies, programs, activities, guidance, regulations, enforcement actions, consent orders, and requirements.” This NPRM provides clarity to registered apprenticeship stakeholders on the Department's plans to implement and align with these Executive Orders and the Administration's priority to promote economic prosperity.

II. Goals of the Rulemaking

In the Department's view, imposing an elaborate set of affirmative action requirements upon registered apprenticeship program sponsors (particularly those that enroll five or more apprentices) is not only administratively burdensome and vulnerable to legal challenge under the laws governing nondiscrimination; it also tends to promote the development of pernicious and divisive group-based preferences within our society, thereby undermining the goal of ensuring equality of opportunity for every individual that participates in the labor force. The Department holds to a more egalitarian vision that is consistent with longstanding American values: that all applicants for registered apprenticeship programs should be evaluated and selected strictly on the basis of individual merit and demonstrated potential, and that a person's race, color, religion, national origin, sex, or age must never be considered by a sponsor as a basis for either rejecting or granting preferential treatment to anyone seeking

admission to a registered apprenticeship program.

Accordingly, this proposed revision to part 30 seeks to ensure genuine equality of opportunity for all persons enrolled in (or seeking admission into) an apprenticeship program by restoring the original focus and purpose of the 1963 version of the regulation: namely, to require that all registered apprenticeship programs be operated on a nondiscriminatory basis. To realize this goal, the proposed revision to part 30 would reaffirm the obligation of sponsors to conduct their apprenticeship programs in accordance with all applicable Federal and State laws governing nondiscrimination in the workplace, while also rescinding the provisions of the current regulation that obligate sponsors to engage in legally questionable affirmative action practices. This proposed rebalancing of the regulation would thus bring the content of part 30 into alignment with the governing law on nondiscrimination and, at the same time, substantially reduce the administrative burdens placed on program sponsors.

A. Revising 29 CFR Part 30 Regulation To Align With Governing Nondiscrimination Law

Recent Supreme Court Rulings Regarding Nondiscrimination Law

In light of recent Supreme Court decisions addressing the use of racial preferences in admission selections, the Department believes that the affirmative action obligations in part 30 imposed on registered apprenticeship sponsors with five or more apprentices are legally vulnerable, and should be rescinded. As the Court stated in *Students for Fair Admissions (SFFA) v. President and Fellows of Harvard College*, “[d]istinctions between citizens solely because of their ancestry are by their very nature odious to a free people whose institutions are founded upon the doctrine of equality.” 600 U.S.181, 208 (2023) (hereinafter *SFFA*). This principle, according to the Supreme Court, “cannot be overridden except in the most extraordinary case.” *Id.* While the current version of the part 30 regulation requires that apprentice selections be made on a nondiscriminatory basis, other provisions within the regulation may incentivize and induce sponsors with five or more apprentices in their programs to consider characteristics like race, ethnicity, and sex when making employment decisions concerning apprentices. This creates an untenable legal conflict where sponsors are required to operate their programs on a

¹⁴ See, e.g., *Students for Fair Admissions, Inc. v. President and Fellows of Harvard College*, 600 U.S. 181 (2023) (holding that race-conscious admissions policies violate the Equal Protection Clause); *Muldrow v. City of St. Louis*, 601 U.S. ___ (2024) (clarifying the threshold for employment discrimination claims under Title VII); *Groff v. DeJoy*, 600 U.S. 447 (2023) (strengthening religious accommodation standards under Title VII); and *Ames v. Ohio Dep't of Youth Servs.*, 605 U.S. ___ (2025) (addressing burdens in proving disparate treatment in employment).

nondiscriminatory basis, while being simultaneously incentivized and induced to engage in the disparate treatment of applicants.

The affirmative action provisions currently found in part 30 require covered sponsors to establish specific numerical goals for the inclusion of women and racial and ethnic minorities in the program based on their prevalence in the local labor force. These statistical goals are imposed without regard to the many nondiscriminatory factors that may explain demographic disparities between an employer's workforce and the demographics of the available local labor market—and without any finding that the sponsor has engaged in unlawful discrimination. Sponsors that fail to demonstrate a “good faith” effort to meet these goals may face enforcement actions, including the possible deregistration of the apprenticeship program by a Registration Agency. However, part 30's regulatory mandate that a program sponsor adopt placement goals based on race and sex could be considered, in the absence of a finding of discriminatory conduct, vulnerable to legal challenge.

In the Department's view, the non-remedial affirmative action requirements in part 30 effectively place a finger on the scale for certain apprenticeship applicants based on their race, ethnicity, or sex—without any showing that a given sponsor has engaged in discriminatory conduct warranting remedial action. These provisions raise legal concerns similar to those addressed by the Supreme Court in *SFFA*, where the Court rejected college affirmative action programs that “concluded, wrongly, that the touchstone of an individual's identity is not challenges bested, skills built, or lessons learned but the color of their skin.” 600 U.S. at 215–216, 231. Regulations that incentivize and induce the adoption of certain practices that can lead to disparate treatment in employment decisions based on race, color, ethnicity, or sex “cannot be reconciled with the guarantees of the Equal Protection Clause.” *Id.* at 230. As such, they must be rescinded.

A similar principle was affirmed in *Ames v. Ohio Department of Youth Services*, 605 U.S. __, (2025) (slip op.), where a unanimous Supreme Court held that, “[a]s a textual matter, Title VII's disparate-treatment provision draws no distinctions between majority-group plaintiffs and minority-group plaintiffs. Rather, [42 U.S.C. 2000e–2(a)(1)] makes it unlawful ‘to fail or refuse to hire or to discharge *any individual*, or otherwise to discriminate against *any*

individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individual's race, color, religion, sex, or national origin’ (emphasis added).” Thus, even if the use of placement goals or action-oriented measures could potentially be justified on a theory of underutilization under *Ames*, there is no legal justification for limiting the placement goals and action-oriented measures to only women and minorities. As Justice Jackson's opinion in *Ames* explains, Supreme Court caselaw has long been “clear that the standard for proving disparate treatment under Title VII does not vary based on whether or not the plaintiff is a member of a majority group.” *Id.* at *6. Similarly, nothing in the NAA justifies creating different standards or regulatory requirements for women or minorities or treating race and sex differently from the other protected categories of religion and national origin. If men, whites, or persons of a particular religion or national origin were also being underutilized based on the DOL's statistical regulatory formula, the regulations failed to impose any affirmative action measures or require placement goals to ensure persons with those characteristics were entitled to equal opportunity in employment.

Moreover, the Department's prior rationale for establishing non-remedial affirmative action requirements on employers and sponsors rested on the abstract premise that an employer's or sponsor's workforce should mirror the demographic composition of the available local labor force—even in the absence of any evidence that disparities were caused by unlawful discrimination. This theory relied on a set of unsupported assumptions. In reality, there are numerous nondiscriminatory factors that may explain differences between a sponsor's workforce and the available local labor force, including applicant interest, qualifications, geography, industry-specific dynamics, and other variations on an individualized basis. Nevertheless, the current regulation imposes demographic utilization goals and compliance obligations on sponsors without accounting for these legitimate variables. And apart from the flawed foundational premise of the rationale, the statistical analyses that sponsors are required to undertake in determining whether utilization goals are required by regulation rely on inconsistent line drawing in determining what is the relevant recruitment area against which to compare the sponsor's apprenticeship program workforce. That sponsors and

not the registration agency are the ones who determine the relevant recruitment area pursuant to the regulations does not make this exercise any less inconsistent. It is actually more inconsistent given that two similarly situated apprenticeship sponsors in the same geographic area could select different geographic lines for the relevant recruitment area analysis—and as a result, one sponsor could conclude that utilization goals are regulatorily required and the other sponsor could conclude those measures are not regulatorily required. The potential unlike outcomes between similarly situated sponsors violates the fundamental principle that regulations should lead to like outcomes between regulated entities.

Streamlining Federal Nondiscrimination Enforcement and Eliminating the Duplicative Oversight and Enforcement Framework in Registered Apprenticeship

The Department's proposal to significantly streamline the part 30 regulation and focus on compliance with existing nondiscrimination laws also reflects its conclusion that a separate oversight, investigative, and enforcement framework specific to registered apprenticeship is not necessary. While the current part 30 regulation imposes substantial administrative burdens—which may deter employers from registering apprenticeship programs—it has not demonstrated clear benefits in terms of improved protections against unlawful discrimination for apprentices. The Department has determined that the costs and disadvantages of maintaining this duplicative and complex regulatory framework—including complex burdens, stakeholder confusion, and a chilling effect on program participation—outweigh any potential benefits. As such, if finalized as proposed, this rule would eliminate redundant requirements while preserving core legal protections through existing Federal and State nondiscrimination enforcement systems.

Part 30 was originally intended to ensure that registered apprenticeship programs operated on a nondiscriminatory basis, with deregistration available as a remedy for noncompliance. However, the Department's historical records show that it has never initiated deregistration proceedings against a sponsor based on a violation of part 30. Although the Department has received a relatively small number of complaints over the years from apprentices alleging

instances of discrimination, its longstanding practice has been to refer such complaints to the Equal Employment Opportunity Commission (EEOC), the Federal agency with primary authority to enforce Federal laws that prohibit discrimination against employees and job applicants.

Regardless of part 30, any employee of, or job applicant for employment with, a covered employer in the United States—including apprentices—may file a charge of unlawful discrimination with the Equal Employment Opportunity Commission (EEOC) against covered employers. Apprentices may also seek relief through other established enforcement entities, such as State fair employment practice agencies or State attorneys general offices. These enforcement bodies are better positioned than Registration Agencies (OA or SAAs) to investigate discrimination allegations and facilitate appropriate resolution. Under the Department's proposal, OA would retain the authority to deregister an apprenticeship program if a competent enforcement agency or court issues a final determination of unlawful discrimination.

Modernizing the Federal Apprenticeship Regulations To Maintain Consistency With Applicable Nondiscrimination Laws

As discussed above, part 30 not only imposes significant administrative burdens on registered apprenticeship program sponsors, but also creates legal uncertainty in light of applicable nondiscrimination law. Many of its requirements—such as establishing utilization goals based on race and other demographic characteristics—closely resemble policies that have been struck down by the Supreme Court for inserting impermissible racial preferences into selection processes (e.g., *SFFA*). As a result, the Department has concluded that part 30 regulation is increasingly misaligned with, and in some respects contrary to, current nondiscrimination law.

Moreover, part 30 regulation reflects a static and prescriptive framework that lacks the flexibility to evolve and adapt. Its requirements are duplicative of existing Federal and State protections provided in nondiscrimination law, ineffective in achieving their intended goals, and in some cases, legally questionable. To address these concerns, the Department proposes replacing the current part 30 regulatory structure with a simplified standard: that all registered apprenticeship sponsors must comply with applicable Federal and State laws prohibiting

discrimination based on race, color, religion, national origin, sex, age (40 or older), genetic information, or disability. By anchoring the nondiscrimination obligation to existing legal authorities concerning nondiscrimination, the proposed approach ensures that registered apprenticeship programs remain aligned with the full scope of civil rights protections—without the need for continual regulatory revisions.

With respect to the requirement contained in § 30.7 of the current regulation that establishes a 7 percent utilization goal for the employment of qualified individuals with disabilities as apprentices, the Department's experience in administering the disability AAP provisions has shown them to be overly burdensome for sponsors who struggle to understand the complex steps of conducting the workforce and utilization analyses, as well as the requirements surrounding the request for and maintenance of self-identification information. In line with the directives of Executive Orders 14192 and 14278, the Department is proposing to remove these regulatory burdens that impose costs on stakeholders and serve as barriers inhibiting broader sponsor participation in the registered apprenticeship system. The Department is therefore proposing to remove these requirements.

The utilization goal also raises the risk that employers will engage in pre-employment disability-related inquiries of apprentice applicants before a conditional job offer is made, which is generally not allowed by the Americans with Disabilities Act.

B. Implementation of Recent Executive Orders Pertaining to Federal Regulations and Apprenticeship

President Trump has recently issued a number of Executive Orders intended to advance the Administration's goals of building a skilled workforce, unleashing prosperity, removing restraints on national economic growth through deregulation, and restoring merit-based opportunity. The Department is committed to developing strategies and enacting bold changes to align its programs and policies with the Administration's policy directives. The Department's proposal to streamline the part 30 regulation for registered apprenticeship represents a critical, strategic policy change that addresses policy directives across several of the Administration's Executive Orders, as discussed below.

In E.O. 14192, *Unleashing Prosperity Through Deregulation*, 90 FR 9065 (issued on January 31, 2025), the President directed Federal agencies to

assess their regulations and pursue deregulatory actions to eliminate regulations that impose costs, create confusion, hamper innovation, or otherwise restrain economic growth and opportunities for Americans. The Department has applied this lens to its programs and their governing regulations and has identified a wide range of deregulatory actions to support the Administration's deregulatory policy priorities, including this proposal to substantially revise and streamline the part 30 regulation. The proposed rule would eliminate eleven entire sections of the part 30 regulation, including sections on affirmative action plans that contain various burdensome requirements for program sponsors. The Department's proposed part 30 regulation would only contain one straightforward requirement for program sponsors—that they comply with all applicable Federal and State nondiscrimination laws—which would not impose any additional costs for sponsors. The Department's analysis of the potential cost savings associated with its proposal to remove all part 30 requirements beyond the streamlined nondiscrimination requirement estimates that sponsors and Registration Agencies would save over \$65 million per year.¹⁵ This significant cost savings, along with the increased clarity for the regulated community that would result from streamlining the part 30 regulation, aligns with the Administration's deregulatory policy directives as stated in E.O. 14192.

In E.O. 14173, *Ending Illegal Discrimination and Restoring Merit Based Opportunity*, 90 FR 8633 (Jan. 31, 2025), the President maintained that his Administration was committed to enforcing, for the benefit of all Americans, the protections contained in longstanding civil rights laws that prohibit discrimination based on race, color, religion, sex, and national origin. At the same time, the President stated in the E.O. that the utilization of pernicious race- and sex-based preferences and policies by the Federal Government and other influential institutions of American society not only contravenes the letter and spirit of these civil rights laws, but also operates to undermine the traditional American values of individual initiative, excellence, and hard work. Accordingly, section 2 of E.O. 14173 directs all executive departments and agencies “to

¹⁵ For the methodology of this estimate, see the cost savings estimated for sponsors from the removal of current part 30 regulations under the proposed rule as described in the cost-benefit description of the proposed rule in the Regulatory Impact Analysis section of this NPRM.

terminate all discriminatory and illegal preferences, mandates, policies, programs, activities, guidance, regulations, enforcement actions, consent orders, and requirements” which operate to undermine the protections against discrimination afforded to individual Americans by longstanding Federal civil rights laws.

In E.O. 14278, *Preparing Americans for High-Paying Skilled Trade Jobs of the Future*, 90 FR 17525 (April 28, 2025), President Trump directed the Secretaries of Labor, Commerce, and Education to develop a plan to reach and surpass 1 million new active apprentices in Registered Apprenticeship programs. The President’s E.O. also expressed the Administration’s commitment to further protecting and strengthening Registered Apprenticeships as a means of unlocking the limitless potential of the American worker.

To facilitate the accomplishment of the Administration’s important policy goals described in the foregoing Executive Orders, the Department is determined to rescind legally questionable regulatory mandates and to reduce, to the extent feasible, any existing administrative and regulatory burdens on employers, apprenticeship program sponsors, SAAs, workforce intermediaries, and other stakeholders. In particular, the Department’s proposed revisions to the part 30 regulation are targeted to remove regulatory requirements that impose onerous administrative burdens and costs on stakeholders, that are misaligned with emergent policy priorities, that unnecessarily expose stakeholders to legal risk, and that inhibit the accelerated establishment and growth of high-quality registered apprenticeship programs.

In evaluating the regulations for registered apprenticeship programs under part 30, the Department has identified provisions that conflict with recent presidential directives and raise legal concerns. Specifically, the requirement that sponsors with five or more apprentices develop affirmative action plans contravenes the directive in E.O. 14173 to “terminate all discriminatory preferences” embedded in federal regulation. Similarly, the reference to “gender identity” that appears in the “equal opportunity pledge” at 29 CFR 30.3(c) of the current regulation is at odds with the policy directives contained in E.O. 14168.

C. Accelerating Growth of the National Apprenticeship System

Growing Registered Apprenticeship To Meet Employer Needs

The Trump Administration has identified registered apprenticeship as a cornerstone of its strategy to build a demand-driven, skilled workforce. As labor market demands continue to evolve, the need for an apprenticeship system that is simultaneously scalable and employer-responsive has become increasingly urgent. In facing that reality, the Department is committed to the exponential expansion of registered apprenticeship—a feat that can only be accomplished through the promulgation of thoughtful regulations free of unnecessary administrative burden.

This rulemaking addresses key structural and regulatory barriers that have long inhibited broader participation in the registered apprenticeship system. Among deterrents to participation in the voluntary system cited by employers, in particular small businesses, are barriers related to compliance with the Equal Employment Opportunity (EEO) regulations at part 30. The simplification of regulatory obligations, while maintaining a strong baseline commitment to nondiscrimination, preserves key protections that serve to safeguard the health and welfare of apprentices. This action serves as a recalibration that will foster expansion, drive employer interest, and bolster registered apprenticeship as the premier workforce development model.

The expansion of registered apprenticeship is predicated on the voluntary participation of employers across a wide range of industries. Stakeholders have long held that the prescriptiveness of part 30 poses a substantial barrier to employer entry and program sustainability. It is certainly understandable how such challenges might be particularly acute for small businesses, which comprise the majority of American employers and figure prominently in the Administration’s economic development agenda. Absent sufficient legal or human resources capacity, many employers have suggested that compliance with part 30 constitutes a significant barrier to participation in registered apprenticeship. In light of these sentiments, DOL is concerned that the continued imposition of the extensive administrative requirements contained in part 30 could restrain the system’s full growth potential and undermine the Department’s ambitious goals to expand the system.

The Department concedes that prescriptive regulatory mandates are antithetical to the promotion and support of an employer-centric model. Creating a compliance environment that is both responsive and adaptive while eliminating unnecessary burden will not only serve to attract additional employers in sectors that have long held strongholds in the registered apprenticeship system but will also be a beacon to employers in new and emerging sectors. By proactively demonstrating an understanding of the operational priorities of employers, the Department increases the likelihood of increased employer buy-in and long-term registered apprenticeship system participation.

As mentioned previously, the registered apprenticeship system has seen consistent growth over the last decade while maintaining strong outcomes, suggesting that the model’s continued growth would provide even more opportunities for Americans to access high-skilled and high-paying jobs.

While construction remains the largest sector for apprenticeships, accounting for approximately 244,858 active apprentices (about 36% of the national total), there has been notable diversification. As of FY 2025, more than 430,000 apprentices are now training in non-construction sectors, including public administration (149,782), educational services (83,777), manufacturing (30,479), and health care and social assistance (18,824). These trends point to growing interest across a wider range of industries—but also highlight where barriers to entry may be limiting broader adoption.

Despite these advancements, a barrier to the further growth and occupational diversification of the apprenticeship model has been the onerous and time-consuming requirements for sponsors to initially receive and consistently maintain registration for an apprenticeship program. In a survey of employers participating in the Department’s American Apprenticeship Initiative (AAI),¹⁶ the mean registration cost per apprentice was found to be over \$1,000, with one employer reporting a cost of over \$12,000 per apprentice.

The current part 30 requirements, such as requiring the development of an affirmative action plan, require

¹⁶ Daniel Kuehn, Sonia M. De La Rosa, Robert I. Lerman, and Kevin Hollenbeck, Abt Associates and Urban Institute, “Do Employers Earn Positive Returns to Investments in Apprenticeship? Evidence from Registered Programs under the American Apprenticeship Initiative,” 2022, https://www.dol.gov/sites/dolgov/files/OASP/evaluation/pdf/AAI-AAI_ROI_Final_Report_508_9-2022.pdf.

substantial staff time and contribute to these significant costs. Many of these costs are also ongoing instead of one-time costs associated with the initial registration of a program. These ongoing costs under part 30 include the requirements to establish an equal employment opportunity (EEO) coordinator (29 CFR 30.3(b)(1)), conduct anti-harassment training (29 CFR 30.4(i)), meet record-keeping requirements (29 CFR 30.12), and (for programs with more than five apprentices) conducting workforce and utilization analyses (29 CFR 30.5(b)).¹⁷ The Department estimated that the current part 30 regulations cost over \$65 million annually. These costs create burdens for the sponsors of apprenticeship programs and disincentivize registering an apprenticeship program.

The current requirements under part 30 also create a perverse incentive to enroll fewer apprentices. Since sponsors with fewer than five apprentices are exempt from the affirmative action plan requirements under part 30, the current regulation creates a disincentive for sponsors to recruit further apprentices and grow the size of their program. A sponsor may avoid further growing their program to more than five apprentices to avoid having to dedicate staff time and resources to meet the requirements of an affirmative action plan if the program exceeds five apprentices. These costs imposed on sponsors under part 30 are likely more significant for smaller firms who have fewer staff and resources or less expertise in human resource management.

The costs and disincentives created by the current part 30 regulations may also be greater in new and emerging industries that are less familiar with the requirements of registered apprentices. Without familiarity of the registered apprenticeship system or contacts within their industry to demystify the process, potential sponsors in these newer industries may need to spend more time to research the existing requirements and how to comply with the highly complex regulatory requirements mandated by part 30. Sponsors and employers in these newer industries may also overestimate the time and resources needed to comply with the requirements under part 30 because of their unfamiliarity and may forgo developing or registering an apprenticeship program altogether because of concerns about the

compliance burden and resources needed.

Streamlining part 30 to focus on ensuring registered programs to comply with existing laws would eliminate these burdens and program registration barriers for sponsors and employers and remove perverse incentives that may artificially limit the number of apprentices served by each program. These proposed changes to part 30 would ultimately help further accelerate the overall growth of the registered apprenticeship model and allow it to spread to additional industries less familiar with the system, and with fewer barriers.

Benefits of Reduced System Bifurcation

To further its commitment to building a modern and cohesive National Apprenticeship System that delivers high-quality training and career pathways to all American workers, this proposed rulemaking also aims to actively address the key challenge of bifurcation between states operated under the direction of the OA States and those operated by federally recognized SAA States. While this dual structure has been foundational to increased flexibility throughout the system, it has also led to divergent standards and operational inconsistencies that hamper compliance due to varying interpretations of part 30 regulatory requirements.

By revising part 30 to prioritize nondiscrimination and remove both legally suspect and burdensome reporting requirements, the Department will strengthen standards alignment and reduce systemic fragmentation while promoting universal participation. Streamlining the existing part 30 requirements—particularly those that have proven difficult to implement uniformly across State systems—will lessen the regulatory disparities that have driven bifurcation and uneven access across the national system.

The NAA allows for both federal and state-level administration of registered apprenticeship programs. In OA States, direct oversight of the state's registered apprenticeship system is the exclusive responsibility of the Department, including the enforcement of the requirements outlined in current part 30. In SAA States, State entities recognized by the Department are responsible for oversight of registered apprenticeship programs, in accordance with State-specific laws or regulations that conform with Federal regulation, including the registration of programs for both State and Federal purposes.

In practice, variances in application of the complex part 30 requirements have

persisted between OA States and SAA States. In some SAA States, different constructions of State laws and regulations pertaining to EEO in apprenticeship have resulted in divergent sets of rules and requirements for registered apprenticeship program sponsors, particularly as it relates to affirmative action plans, collection of demographic information for apprentices, and targeted outreach strategies. Resistance from registered apprenticeship stakeholders compounds those challenges, resulting in registration delays and limited or uneven compliance enforcement. These divergences exacerbate negative perceptions of the registered apprenticeship system—particularly among sponsors operating in multiple jurisdictions—which has negatively impacted apprenticeship expansion.

Through this proposed rulemaking, the Department articulates a unified approach to nondiscrimination in registered apprenticeship and eliminates the requirement for SAA States to establish complex EEO State laws specific to registered apprenticeship that reach beyond nondiscrimination and impose administratively burdensome and legally suspect mandates on apprenticeship sponsors. Adoption of the proposed text will result in OA States and SAA States adhering to identical regulations that align the nondiscrimination standards for apprenticeship sponsors, registered for federal purposes, to all applicable Federal and State nondiscrimination laws, while facilitating the removal of State apprenticeship regulations, laws or policies that impose additional mandates on registered apprenticeship sponsors, and that fail to conform to or exceed what is required under the proposed revision of part 30. The Department recognizes that SAA States have developed their State apprenticeship regulations, laws or policies to conform with the administratively burdensome and legally suspect requirements imposed under the current part 30, and that achieving conformity with the proposed revision of part 30 will require States to update their policies to align with the streamlined regulatory approach to nondiscrimination in registered apprenticeship. While the proposed part 30 will establish an identical regulatory approach to nondiscrimination across the National Apprenticeship system by tying the nondiscrimination standard to compliance with Federal and State nondiscrimination laws, the proposed regulation will achieve the deregulatory

¹⁷ 29 CFR part 30, "Equal Employment Opportunity in Apprenticeship," <https://www.ecfr.gov/current/title-29/subtitle-A/part-30>.

goals of this rulemaking while recognizing States' ability to establish general nondiscrimination laws that apply to entities operating in their jurisdiction. This proposed regulatory approach is intended to promote the cohesion of and prevent unnecessary fragmentation within the National Apprenticeship System, while also encouraging the accelerated adoption of registered apprenticeship by potential sponsors as a proven model for upskilling the workforce.

III. Section-by-Section Discussion

Removing Burdensome Requirements From the Part 30 Regulation Proposed Recission of AAP Requirements (§§ 30.4–30.9 and 30.11)

Affirmative Action Programs (§ 30.4)

Existing § 30.4 requires non-exempt sponsors to adopt affirmative action programs, the components of which are captured at existing §§ 30.4, 30.5, 30.6, 30.7, 30.8, 30.9, and 30.11, and to set forth that program in a written plan.

The affirmative action program requirements include conducting utilization analyses and setting goals if underutilized on the basis of race, sex, and ethnicity. As part of their affirmative action programs, sponsors are also required to review their personnel processes on an annual basis and conduct targeted outreach, recruitment and retention activities. There are also specific requirements related to individuals with disabilities, including measuring progress towards meeting a utilization goal set by OA and inviting applicants for apprenticeship to self-identify as individuals with disabilities.

As a general matter, the Department has determined that the affirmative action components of existing part 30 are unnecessarily burdensome, ineffective, and, in some cases, legally vulnerable. The specific rationale for rescinding each affirmative action component is discussed in the respective sections, below. The Department solicits comments from all interested parties, including registered apprenticeship stakeholders, regarding its proposal to rescind the AAP requirements from the part 30 regulation, particularly the extent to which the administrative burdens associated with AAP requirements have impacted the operation of their program or their decision to participate in registered apprenticeship.

Utilization Analysis for Race, Sex, and Ethnicity (§ 30.5)

Existing § 30.5 requires sponsors maintaining AAPs to assess and

compare the racial, sex, and ethnic representation within each major occupation group of their program to the racial, sex, and ethnic representation available in the sponsor's relevant recruitment area. Pursuant to this section, when the sponsor's utilization of women, Hispanics or Latinos, or a particular racial minority group is significantly less than would be reasonably expected, the sponsor is required to establish a utilization goal for the affected group in accordance with § 30.6.

As discussed above, the Department believes that these provisions that cause sponsors to focus on the race, sex and ethnicity composition of the apprentice workforce are legally vulnerable because they may induce sponsors to engage in illegal race and/or sex-based decision-making in apprenticeship. The AAP requirements to set race, sex, and ethnicity-based goals may have the effect of pressuring sponsors to engage in impermissible discrimination in favor of underutilized groups. The Supreme Court's decision in *SFFA v. Harvard* makes clear that race-conscious selection decisions would be subject to exacting scrutiny, and an apprenticeship system that incentivizes such improper preferences would not survive legal challenge. Furthermore, the Supreme Court's recent decisions in *Ames v. Ohio* and *Muldrow v. St. Louis* held that the standard for proving disparate treatment under Title VII does not vary based on whether or not the plaintiff is a member of a majority group. No. 23–1039, 605 U. S. ____ , (2025) (slip op. at 6). Thus, any individual can bring a discrimination suit under Title VII by demonstrating, as a threshold matter, that he or she suffered "some harm" in relation to an allegation of unlawful discrimination in employment (such as being adversely impacted by an employer's affirmative action policy).

For these reasons, the Department proposes to rescind the affirmative action provisions requiring utilization analysis on the basis of race, sex, and ethnicity.

Establishment of Utilization Goals for Race, Sex, and Ethnicity (§ 30.6)

Pursuant to existing § 30.6, sponsors maintaining AAPs are required to set a utilization goal equal to availability for any racial, sex, or ethnic group that is underutilized in the apprenticeship program. While § 30.6 further states that these goals are not to be used as quotas, preferences, set-asides, or as a basis for departure from merit principles, the Department has determined that the incentive created by this goal-setting

provision creates too great a risk that, in practice, sponsors may use impermissible race and sex-based preferences to meet the utilization goal. Accordingly, the Department is proposing to rescind these requirements.

Utilization Goals for Individuals With Disabilities (§ 30.7)

Existing § 30.7 requires sponsors maintaining AAPs to compare the representation of individuals with disabilities in their program to the 7% benchmark set by the Administrator. Where sponsors determine that their utilization of individuals with disabilities is less than the 7% goal, they must take steps to determine whether and/or where impediments to equal opportunity exist and undertake action-oriented programs designed to correct any problem areas.

The Department's experience in administering the disability AAP provisions (including §§ 30.7 and 30.11, discussed further below) has shown them to be overly burdensome for sponsors who struggle to understand the complex steps of conducting the workforce and utilization analyses, as well as the requirements surrounding the request for and maintenance of self-identification information. Combined with the fact that only approximately 25% of sponsors are required to maintain AAPs, the Department does not feel that these requirements have moved the needle in a meaningful way in terms of data collection or advancing equal opportunity for all apprentices. The Department is also concerned that this requirement may improperly incentivize employers to make unlawful disability-related inquiries prior to extending a conditional job offer.

The Department notes that all sponsors with 15 or more employees remain covered by title I of the Americans with Disabilities Act, 42 U.S.C. 12101, *et seq.*, which provides robust protections against unlawful discrimination of individuals with disabilities in all terms, conditions and privileges of employment. 42 U.S.C. 12112; 29 CFR 1630.4.

In line with the directives of Executive Orders 14192 and 14278, the Department is proposing to remove these regulatory burdens that impose costs on stakeholders and serve as barriers inhibiting broader sponsor participation in the registered apprenticeship system. The substantial staff time required to collect the self-identification information and conduct the accompanying utilization analyses are ongoing costs and creates a disincentive for sponsors to recruit

further apprentices and grow the size of their program. Accordingly, the Department is proposing to remove these requirements.

Targeted Outreach, Recruitment, and Retention (§ 30.8)

Existing § 30.8 requires sponsors that have found underutilization to undertake targeted outreach, recruitment, and retention activities that are likely to generate an increase in applications for apprenticeship and improve retention of apprentices from the targeted group or groups and/or from individuals with disabilities, as appropriate. As these activities are targeted to be race and/or sex-conscious, the Department believes that these required activities present the same legal risks as those posed by the utilization goals based on race, sex, and ethnicity. These requirements may put “official pressure” upon sponsors to recruit candidates of a particular race, sex, or ethnicity and thus subject persons of different races to unequal treatment by inducing sponsors to use limited recruiting resources only to the benefit of certain minority groups. *MD/DC/DE Broadcasters Ass’n v. FCC*, 236 F.3d 13, 15, 20–21 (D.C. Cir. 2001), *cert. denied*, 534 U.S. 1113 (2002).

Thus, for the same reasons discussed in § 30.5, the Department is proposing to rescind these requirements.

Review of Personnel Processes (§ 30.9)

Existing § 30.9 requires sponsors maintaining an AAP to engage in an annual review of their personnel processes related to the administration of their apprenticeship program to ensure that the program is free from unlawful discrimination.

Similar to other AAP provisions, the Department has found this requirement to be unnecessarily burdensome and confusing to sponsors. Most sponsors are subject to federal and State nondiscrimination laws and likely already have their own mechanisms and reviews in place to ensure compliance with those laws. The Department does not need to prescribe an overly detailed and onerous method for doing so; rather, the Department trusts sponsors to determine the best means of ensuring compliance with nondiscrimination laws for their program. This approach will allow for sponsor innovation, avoids a one-size-fits-all scheme, and would align with the Administration’s policy to “significantly reduce the private expenditures required to comply with Federal regulations to secure America’s economic prosperity” E.O. 14192. This flexibility will also prevent duplication of

nondiscrimination compliance efforts already being made by employers that participate in registered apprenticeship programs.

Invitation To Self-Identify as an Individual With a Disability (§ 30.11)

Existing § 30.11 requires sponsors maintaining an AAP to invite applicants and current apprentices to identify as an individual with a disability.

For the reasons discussed above at § 30.7, the Department has found this requirement to generate confusion among sponsors and SAAs, and has resulted in greater burden than expected on sponsors as they attempt to comply while simultaneously maintaining apprentice confidentiality and engaging with the Registered Apprenticeship Partners Information Data System (RAPIDS) system. Because the Department has concluded that the burden and confusion caused by this requirement outweighs any benefit from the invitation—due to limited and unreliable data collection—the Department now proposes to rescind it.

Proposed Rescission of 30.10, Selection of Apprentices

The Department proposes to rescind § 30.10, which governs how sponsors may select apprentices. The section provides that sponsors may use any method of combination of methods for selection of apprentices provided the method(s) meet the criteria set out in the section. These provisions are duplicative of Title VII’s prohibition against discrimination in selections, and thus are unnecessary. Title VII contains detailed prohibitions against unlawful employment practices, including practices related to selection. See 42 U.S.C. 2000e–2. Additionally, current § 30.10 contains requirements that exceed what is required by Title VII. Specifically, the Uniform Guidelines on Employee Selection Procedures (UGESP)—with which current § 30.10 requires compliance—only provides guidance for EEOC and employers regarding the validity of selection procedures. See 29 CFR 1607.1 (“These guidelines incorporate a single set of principles which are designed to assist employers . . . to comply with the requirements of Federal [nondiscrimination] law”); *Equal Emp. Opportunity Comm’n v. Crothall Servs. Grp., Inc.*, No. CV 15–3812, 2016 WL 3519710, at *7 (E.D. Pa. June 28, 2016) (internal citations omitted) (courts have found nonbinding “UGESP’s discretionary principles for determining the validity of selection procedures,” in contrast to its recordkeeping requirement). This inconsistency

between OA and Title VII standards, which sponsors also currently must follow, has created confusion for sponsors. This proposal removes the conflicting framework that was created by existing § 30.10.

The Department’s proposed approach eliminates § 30.10 in favor of a single, consistent requirement that sponsors comply with applicable federal and State nondiscrimination laws. The proposal eliminates the requirement that employers use a more proscriptive selection procedure for apprentices than they would for other employees. This will reduce compliance complexity and legal uncertainty while preserving strong protections against discriminatory selection practices. It will also reduce confusing and burdensome requirements that deter sponsors from participating in registered apprenticeship, in line with the Department’s goal of growing high-quality, skills-based career pathways, including apprenticeship opportunities in new sectors.

Proposed Rescission of 30.17, Intimidation and Retaliation Prohibited

The Department proposes to rescind § 30.17, which prohibits intimidation, and retaliation against individuals exercising rights under part 30. While the Department supports protections against retaliation, similar protections are already well-established and enforceable under existing federal and State civil rights laws.

Maintaining a separate, apprenticeship-specific retaliation provision is both duplicative and legally unnecessary. The Department believes it is more appropriate and effective for such allegations to be addressed by agencies with jurisdiction and enforcement authority under those statutes, such as the EEOC.

Accordingly, the Department proposes to remove § 30.17 and instead require sponsors to comply with all applicable laws prohibiting retaliation and interference, thereby streamlining the regulatory framework while preserving robust protections for apprentices.

A. The Revised Part 30 Regulation—Prohibiting Illegal Discrimination in Registered Apprenticeship

Section 30.1—Purpose and Applicability

The “Purpose and Applicability” introductory section of the proposed rule would substantially revise and streamline the content of the corresponding “Purpose, applicability, and relationship to other laws”

provision that is found at section 1 of the current part 30 regulation. Among other things, the revised § 30.1 would, consistent with the policies and rationales outlined and described above, remove all references to affirmative action efforts and would also dispense with redundant and repetitive language pertaining to protected bases and complaint processes, each of which are addressed fully in later sections of the updated regulatory text. The revised § 30.1 states clearly that the purpose of the part 30 regulation is to “establish a uniform Federal standard prohibiting illegal discrimination against apprentices (including applicants for apprenticeship) in registered apprenticeship programs,” as well as assert that the nondiscrimination requirements are applicable to program sponsors and SAAs. The revised purpose section also notes that the revised rule seeks to provide clarity to the foregoing interested parties regarding the scope and content of compliance reviews, compliance assistance, and enforcement actions by Registration Agencies.

Section 30.2—Definitions

This section of the proposed rule would delete all of the definitions that are set forth in the current part 30 regulation and would adopt by reference each of the applicable existing definitions found in the labor standards of apprenticeship regulation at 29 CFR part 29. The Department has determined that each of the definitions contained in 29 CFR 30.2 are either duplicative of existing definitions found at 29 CFR 29.2 or have been rendered unnecessary or obsolete by the extensive revisions to the substantive provisions of part 30 made in this proposal. The Department believes that the resulting consolidation of all apprenticeship-related definitions within the existing regulatory text of 29 CFR part 29 will lessen the administrative burdens on registered apprenticeship program sponsors and other interested parties by providing a single definitional reference point within the Federal apprenticeship regulations. The Department invites comments from all interested parties on the proposed consolidation of definitions in part 29, including whether the Department should include any additional definitions based on the content of this proposed rule.

Section 30.3—Nondiscrimination Standards Applicable to All Sponsors

Section 30.3 of the proposed rule obligates every sponsor of a registered apprenticeship program to comply with all applicable Federal and State laws

and regulations that prohibit illegal discrimination on the basis of race, color, religion, national origin, sex, age (40 or older), genetic information, or disability. The Department notes that the foregoing list of protected bases upon which registered apprenticeship sponsors may not discriminate is fully consistent with the content and scope of currently applicable Federal civil rights statutes, including Title VII of the Civil Rights Act of 1964 and its subsequent amendments, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, as amended, and the Genetic Information Non-Discrimination Act of 1998. This proposed regulatory provision further stipulates that a failure by a registered apprenticeship program sponsor to comply with applicable Federal and State nondiscrimination laws may constitute grounds for enforcement action or deregistration proceedings by a Registration Agency pursuant to § 30.5 of the proposed rule, provided that such non-compliance is related to illegal discrimination against an apprentice (or an applicant for apprenticeship) with respect to any benefit, term, or condition of employment associated with an apprenticeship. The Department has an interest in only conferring the benefit of registration upon sponsors that operate in a manner fully compliant with the applicable laws governing nondiscrimination. Accordingly, the Department is confident that this straightforward and streamlined regulatory provision will facilitate the realization of this fundamental policy objective.

Section 30.4—Complaints

The Department proposes to rescind the provisions covering complaints in the existing part 30 regulation. In its place, the Department proposes a significantly streamlined complaints framework at proposed § 30.4, which would clarify that the Registration Agency will refer any individuals alleging unlawful discrimination to an enforcement agency with appropriate jurisdiction over, and expertise in, investigating compliance with Federal or State nondiscrimination laws or regulations. Such entities include the EEOC, the U.S. Attorney General or a State Attorney General, or an applicable State enforcement agency (e.g., a Fair Employment Practices Agency).

The Department has determined that the existing regulatory requirements for part 30 complaints represent a cumbersome, confusing, and ineffective framework that is much less capable of investigating or resolving issues arising from apprentice complaints alleging

discrimination than the enforcement entities outlined in proposed § 30.4 and described in this NPRM.

Based on its experience overseeing the National Apprenticeship System and implementing the part 30 regulatory requirements over the past eight years, the Department has determined that maintaining a separate and unique discrimination complaint framework for apprenticeship does not serve apprentices' interests and does not align with the Administration's explicit directive to remove burdensome regulatory requirements and promote flexibility for stakeholders of programs overseen by Federal agencies. The Department recognizes that requiring that apprentices file complaints through an official form unique to the apprenticeship system (the OMB-approved ETA Form 9039) is overly prescriptive, limiting, and may cause confusion for apprentices in knowing the agency from which to seek relief. The Department further recognizes that prescribing other requirements for complainants (such as dictating who may file and the time period for filing) and program sponsors (such as the requirement that sponsors communicate their program's complaint policy using specific “notice” language prescribed at 30.14(b)) only serves to delay and dilute any potential relief for apprentices alleging violations pertaining to illegal discrimination. Accordingly, the Department proposes to rescind the existing complaint provisions at 30.14(a) and (b) which prescribe complaint requirements for apprentices and sponsors.

The existing part 30 regulation also established an extensive set of requirements for the Registration Agencies in the part 30 complaints framework. In response to complaints received, the Department has either referred or investigated each complaint according to the process set forth at current 30.14(c)(1). The Department acknowledges that Registration Agency staff lack the capacity and expertise to investigate workplace discrimination and is unaware of any evidence that their involvement in apprenticeship-related complaints has provided meaningful protections for apprentices. Accordingly, the Department proposes to rescind the existing requirements for Registration Agencies at current 30.14(c). Instead, the Department proposes to replace the existing, extensive requirements for part 30 complaints with a simple and clear requirement explaining what Registration Agencies are to do if they receive discrimination complaints (*i.e.*, refer the individual to an appropriate

enforcement agency with jurisdiction over the complaint, such as the EEOC).

The Department believes such a streamlined and simplified approach to discrimination complaints in registered apprenticeship would preserve Federal and State enforcement, oversight, and investigative resources, and would align with the Administration's directives to undertake deregulatory actions where existing regulations impose unnecessary and burdensome requirements. Most importantly, the Department believes that clarifying the most appropriate and effective avenue for filing discrimination complaints and pursuing relief from any discriminatory actions would be in apprentices' best interests and would align with the Department's guiding statutory mandate to protect apprentices' welfare.

Section 30.5—Nondiscrimination Compliance Reviews and Enforcement

In addition to the proposed removal of the extensive EEO and affirmative action requirements found in the current version of part 30, the Department proposes to modify the compliance and enforcement framework that is set forth in § 30.13 and § 30.15 of the existing regulation by streamlining and consolidating these provisions under a new provision (§ 30.5) of the proposed rule. Currently, the Department conducts regular "EEO compliance reviews" to assess sponsors' compliance with the extensive requirements found throughout the existing part 30 regulation, with a particular focus on the development and implementation of an AAP that is required for programs with five or more apprentices under current § 30.4 (the specific contents of which are set forth in § 30.5 through § 30.9 and in § 30.11 of the current rule). The existing part 30 regulation also includes various additional requirements applicable to all sponsors that the Department proposes to rescind, including the obligation that sponsors maintain extensive records pertaining to the full suite of current part 30 requirements, invite apprentices to self-report their disability status at registration and annually thereafter, and post an "EEO Pledge" with specific wording in a visible location at the program's worksite(s), among others. As discussed at length in this preamble, the Department has determined that it is unnecessarily burdensome and confusing, to impose an extensive set of nondiscrimination, EEO, and affirmative action requirements on registered apprenticeship sponsors, and that the perpetuation of such onerous regulatory requirements will only serve to inhibit

the accelerated expansion of registered apprenticeships. Accordingly, the Department proposes to revise and consolidate the content of the existing § 30.13 and § 30.15 by combining the compliance reviews and enforcement actions elements of the proposed part 30 regulation within a new section—"Nondiscrimination compliance reviews and enforcement." The subjects covered by this new section of the proposed rule would align closely with the overarching policy focus of the streamlined part 30—that sponsors must operate their program in a completely nondiscriminatory manner.

In the context of registered apprenticeship, the Department is committed to focusing its resources—including staff expertise—on matters pertaining to the quality of apprenticeship programs. As subject-matter experts in the various apprenticeship program-related topics that are set forth in the "Labor standards for the registration of apprenticeship programs" regulation at 29 CFR part 29, Registration Agency staff have the knowledge and experience to assess registered apprenticeship program quality. Registration Agency staff, who are focused primarily on matters pertaining to apprenticeship quality, are not well-positioned, and are not suitably equipped, to make the legal determinations¹⁸ necessary to assess registered apprenticeship programs' adherence to the elaborate nondiscrimination, EEO, and affirmative action requirements found in the existing part 30 regulation. Accordingly, the Department proposes eliminating these extensive requirements and substituting in their place a clear, universal standard of compliance with applicable Federal and State nondiscrimination laws for all registered apprenticeship programs.

To assess program compliance with this revised and consolidated regulatory provision, the Department proposes to rely solely on final determinations made by courts. These entities are equipped with the necessary competencies and resources, along with the applicable authority and jurisdiction, to

investigate, adjudicate, and impose remedial actions in response to allegations of discrimination in employment. The Department expects that relying on the expertise and authority of such entities to determine whether sponsors (or other apprenticeship stakeholders, such as an employer participating in a registered apprenticeship program) have engaged in illegal discrimination in violation of applicable Federal or State statutes or regulations will lead to a more efficient compliance and oversight framework, improved accountability, greater clarity for stakeholders, and more relevant and effective relief for any victims of unlawful discrimination, harassment, or other illegal treatment in the registered apprenticeship context.

Under proposed § 30.5(a), the Department proposes that compliance reviews for the streamlined part 30 nondiscrimination requirement would occur concurrently with a registered apprenticeship program's normal program review to assess compliance with part 29. At proposed § 30.5(b), the Department sets forth the process for determining sponsors' compliance with the streamlined nondiscrimination requirement and the threshold for initiating enforcement actions. The Department proposes that Registration Agencies may only initiate enforcement actions over a violation of the part 30 nondiscrimination requirement when a final determination of a violation of applicable nondiscrimination laws or regulations is made pertaining to an apprentice or applicant for an apprenticeship, without any remaining right to appeal, by a court with jurisdiction over allegations of discrimination in employment (including alleged discrimination against apprentices or an applicant to apprenticeship program). Such an approach is intended to ensure that a Registration Agency does not act on any complaints while such matters are being adjudicated, which is consistent with due process principles. Proposed § 30.5(c) describes the process for Registration Agencies to initiate enforcement, which includes working with the sponsor to develop a compliance action plan that aligns with the remedy for the alleged discrimination prescribed by the court, and brings the program into compliance with the part 30 nondiscrimination requirement. Under proposed § 30.5(c), Registration Agencies may pursue further enforcement actions, including the suspension of the sponsor's right to register new apprentices or the initiation of formal deregistration

¹⁸ Under the current regulation, such legal determinations include assessing: whether a sponsor's selection procedures are "facially neutral" or whether sponsors have adequately assessed their selection procedures' impact on race, sex, and ethnic groups per the Uniform Guidelines on Employee Selection Procedures (per current § 30.10); whether sponsors' affirmative outreach, recruitment, and retention plans have been effective in meeting sponsors' utilization goals (per current §§ 30.6, 30.8); and whether allegations of discrimination have violated applicable antidiscrimination requirements (per current § 30.14).

proceedings (set forth at 29 CFR 29.8), if the Registration Agency determines that the sponsor is not implementing the compliance action plan according to the remedy prescribed by the court.

The Department believes that this streamlined approach to compliance and enforcement of the part 30 regulation would preserve Registration Agencies' critical role in conferring the benefit of program registration, and in rescinding registration when such enforcement is necessary.

Section 30.6—Reinstatement of Program Registration

The Department proposes to retain the "Reinstatement of program registration" provision from the existing part 30 regulation at current § 30.16. The Department has determined that its proposal to streamline and simplify the part 30 regulation should retain a provision allowing sponsors to seek and receive reinstatement of their program registration if they demonstrate, to the satisfaction of the Registration Agency and the relevant court which issued a final determination confirming a violation of an applicable nondiscrimination statute or regulatory requirement that the apprenticeship program is being operated in accordance with this part. The Department retains the existing provision's language that sponsors must present "adequate evidence" that they are operating in compliance with part 30. Under the framework proposed in this NPRM, any violations of part 30 would be confirmed by a court of competent jurisdiction over nondiscrimination in employment statutes or regulations; accordingly, the Department would require sponsors to provide adequate evidence that they have alleviated any issues giving rise to the nondiscrimination complaint to the satisfaction of the court, including implementing any remedial actions. The Department has determined that keeping a regulatory provision on the reinstatement of a program's registration aligns with the proposed compliance framework and the Department's goal, in streamlining the regulation, to promote regulatory flexibility for registered apprenticeship stakeholders.

Section 30.7—State Apprenticeship Agencies

The Department proposes to rescind parts of current § 30.18, the provision covering State Apprenticeship Agencies in the existing part 30 regulation. Existing regulatory requirements for SAAs under part 30 have been ineffective in setting a consistent standard for nondiscrimination in

registered apprenticeship. As evidenced by varying degrees of conformity with existing § 30.18, the current part 30 regulation has not been fully successful in achieving a uniform national standard for nondiscrimination in registered apprenticeship and equality of opportunity. For instance, existing § 30.18(a) requires that an SAA have a State EEO Plan that "at a minimum" includes "draft State apprenticeship language corresponding to the requirements of this part." This language has created inconsistencies across SAAs. In its place, the Department proposes a new § 30.7 that would eliminate burdensome and legally suspect administrative requirements for SAAs, including the requirements for State-specific laws that exclusively apply to nondiscrimination in registered apprenticeship; the Department believes that such State laws specific to registered apprenticeship only serve to complicate and splinter the National Apprenticeship System. Accordingly, § 30.7 would facilitate the establishment of a uniform standard governing nondiscrimination in registered apprenticeship and reduce SAA administrative burdens by stipulating that compliance with applicable federal and State nondiscrimination laws is sufficient to conform with the requirements of the updated part 30.

Proposed § 30.7(a) requires that, within one year of the effective date of the final rule, all SAAs seeking to obtain or maintain recognition under current § 29.13 must ensure that their apprenticeship laws, regulations, policies, and procedures exclusively pertain to nondiscrimination and equality of opportunity for apprentices "conform only to the requirements of this part [30]." This proposed provision would relieve SAA States from having to impose the complex, burdensome, and legally suspect set of regulatory obligations that are found in current version of part 30 and would substitute a straightforward requirement that such states conform to the nondiscrimination requirements found in applicable federal and State laws. Accordingly, the purpose of this proposed provision is to establish a nationally uniform standard for nondiscrimination protections across all States participating in the National Apprenticeship System. The establishment of such a uniform standard at proposed § 30.7(a) seeks to ensure that State laws and regulations concerning nondiscrimination and equality of opportunity in registered apprenticeship are coextensive in their substance and scope with the

requirements of revised part 30 and consistent with federal and State nondiscrimination laws; the attainment of such a result would be particularly helpful for sponsors that register and operate their programs in multiple States, and would foster an environment that is conducive to accelerating the expansion of registered apprenticeship programs. In addition, the allowance of a "good cause" extension stipulated by proposed § 30.7(a) would allow needed flexibility for States with differing legislative or regulatory processes to enact and implement laws that conform only to the requirements stipulated herein.

Proposed § 30.7(b) and related subsections set forth the elements of State Plans for nondiscrimination in apprenticeship for States seeking new or continued SAA recognition. Proposed § 30.7(b)(1)(i) stipulates that State plans include all of a State's statutes, regulations, and policies pertaining exclusively to nondiscrimination in apprenticeship, and that they conform only to the requirements of the proposed part 30. This language helps to prevent operational fragmentation within State-registered programs and ensures consistent application of nondiscrimination standards. Proposed § 30.7(b)(1)(ii) further stipulates that all State-registered programs comply with a State's DOL-approved State plan within 180 days from the date that the Department approves the State Plan submitted under proposed (a). The Department believes that a 180-day compliance window ensures an orderly and timely transition to full implementation at the program level, particularly since sponsors must already be operating their apprenticeship program in compliance with the applicable Federal and State nondiscrimination laws. The Department invites comments from all interested parties, and from SAAs in particular, about the proposed timeline for compliance with the revised part 30 requirements.

Proposed § 30.7(b)(2) mirrors the purpose of existing § 30.18(a)(2)(i-iii) as it outlines the review process that OA will undertake upon receipt of the State plan, including provision of technical assistance to support conformity with Federal regulations. Similarly, proposed § 30.7(b)(3) stipulates that if an SAA State does not submit a revised State plan that adequately responds within 90 days to OA's provision of technical assistance on nonconformity issues, OA may initiate derecognition proceedings set forth in § 29.14 and proposed § 30.7(e) to formally derecognize the SAA. This provision is intended to

provide both due process and accountability for the State. Proposed § 30.7(b)(4) reaffirms the requirement of existing § 30.18(a)(4) by proposing that any subsequent amendments to the State Plan for nondiscrimination in apprenticeship are submitted to the OA Administrator for review and approval prior to implementation. This requirement is intended to promote alignment between State plans and the Federal nondiscrimination framework described herein.

The recordkeeping requirements stipulated by proposed § 30.7(c) largely replicate the SAA recordkeeping obligations currently found in § 30.18(b), which require a recognized SAA to keep only records pertaining to program compliance reviews, complaint investigations, and any other records pertinent to a determination of compliance with this part. These records must be maintained for five years from the date of their creation. The proposed provision supports OA's ability to continue overseeing and auditing compliance over time. It also ensures that there is adequate documentation to make informed decisions about SAA recognition status.

Proposed § 30.7(d)(1) states that OA retains full authority to conduct compliance reviews of all registered programs for Federal purposes, even programs registered by an SAA. Similarly, proposed § 30.7(d)(2) reiterates that any SAA that fails to comply with the requirements of this proposed rulemaking is subject to deregistration proceedings as provided in existing §§ 29.8(b) and 29.10. The rescission of existing § 30.18(c)(2) and (c)(4)(i) through (iii) is in accordance with proposed § 30.4 which proposes a significantly streamlined complaints framework. The purpose of these revisions is to more efficiently deploy agency resources while preventing duplication of investigatory efforts with those civil rights enforcement agencies that possess the statutory authority and expertise to conduct such inquiries. Accordingly, under this proposal, the Department would not retain any authority to independently investigate or resolve complaints of discrimination in registered apprenticeship. However, OA retains the authority to refer complaints to appropriate civil rights enforcement agencies (under proposed § 30.4), and to take appropriate enforcement action (under proposed § 30.5) based on another agency's findings regarding discriminatory conduct by apprenticeship program sponsors.

Proposed § 30.7(e) replicates the content of current § 30.18(d). This

derecognition provision may be utilized by the Department in appropriate circumstances to assure full conformity by SAA states with federal nondiscrimination obligations contained in this part.

Section 30.8—Exemptions

The Department proposes to retain the Exemptions provision from the existing part 30 regulation at current § 30.19. The Department's proposed revisions are intended to provide relief to registered apprenticeship stakeholders from burdensome regulatory requirements, and the Department has determined that preserving the part 30 Exemptions provision serves this goal and retains the regulatory flexibility built into the current part 30 regulation. Under the existing provision, which the Department proposes to retain, sponsors must submit requests for an exemption from part 30 requirements in writing to the Registration Agency, which may issue the exemption for good cause. The Department also proposes to retain the requirement that SAAs in receipt of any exemption requests from sponsors in their State must receive approval from OA before granting the exemption. Accordingly, proposed § 30.8 reflects identical regulatory language to the existing provision at § 30.19.

C. Technical and Conforming Edits to Part 29

The Department proposes technical and conforming edits to 29 CFR part 29. The scope of the proposed changes would be narrow and primarily confined to necessary adjustments to align with proposed changes to 29 CFR part 30.

First, the Department proposes to amend various provisions in part 29 to update cross-references and terminology to reflect the proposed revisions to part 30. For example, the Department proposes to revise § 29.3(b)(2) and § 29.5(b)(21) to refer explicitly to the revised nondiscrimination requirements set forth in 29 CFR part 30, as amended. These edits ensure that all registered apprenticeship programs will be subject to the new streamlined nondiscrimination obligations.

Second, the Department proposes revisions to § 29.12 (Complaints) to clarify that complaints alleging illegal discrimination—on the basis of race, color, religion, national origin, sex, age, disability, or other protected characteristics—must be referred by the Registration Agency to the appropriate enforcement authority, as specified in proposed § 30.4. This edit conforms to the proposed part 30 regulatory structure, under which enforcement

actions related to discrimination are handled by agencies with jurisdiction under applicable nondiscrimination statutes, such as the Equal Employment Opportunity Commission (EEOC), the U.S. Department of Justice, or equivalent State-level enforcement agencies.

Third, the Department proposes edits to § 29.7 (Apprenticeship Agreement) to reflect the current statutory language and legal standards governing nondiscrimination. Specifically, § 29.7(j) is revised to prohibit discrimination in apprenticeship on the basis of race, color, religion, national origin, sex, age (40 or older), genetic information, or disability. This ensures consistency with Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Americans with Disabilities Act, and the Genetic Information Nondiscrimination Act.

The Department also proposes to modify the text of the current Section 29.7(l), by removing the specific references to the apprentice's race, sex, ethnicity, and disability status, and replacing these references with a more general request to collect demographic data about the apprentice. The Department has determined that requesting specific types of demographic data, such as the apprentice's disability status, in the Apprenticeship Agreement is not consistent with the Department's proposal. In addition, the Department believes that a more general authorization to request "demographic information" about apprentices would provide greater flexibility for apprenticeship stakeholders and the Registration Agency. Accordingly, the Department proposes a conforming edit to modify section 29.7(l) to replace the specific demographic categories and instead require that the Apprenticeship Agreement simply contain a "request for demographic data about the apprentice."

The Department also proposes edits to provisions governing SAA recognition and operation. Sections 29.13 and 29.14 are revised to require State apprenticeship laws, nondiscrimination plans, and enforcement procedures conform to the streamlined federal requirements in revised part 30. These edits are intended to reduce regulatory bifurcation between OA and SAA states, eliminate inconsistent nondiscrimination standards across jurisdictions, and promote uniformity in the application and enforcement of apprenticeship regulations nationwide.

Finally, conforming changes are proposed throughout part 29 to update

outdated references and clarify that nondiscrimination enforcement responsibilities lie with appropriate civil rights agencies. These include proposed revisions to § 29.11 (Limitations) to reflect applicable law and Executive Orders, and updates to recordkeeping provisions in §§ 29.13 and 29.14 to ensure continued access to compliance-related documents by the Department.

IV. Procedural Issues and Regulatory Review

A. Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14192 (Unleashing Prosperity Through Deregulation)

Under E.O. 12866, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) determines whether regulatory action is significant and, therefore, subject to the requirements of the executive order and review by OMB. See 58 FR 51735 (Oct. 4, 1993). This proposed rule is an economically significant regulatory action under section 3(f)(1) of E.O. 12866, and OIRA has reviewed it.

E.O. 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; the regulation is tailored to impose the least burden on society, consistent with achieving the regulatory objectives; and in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. E.O. 13563 recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify.

The Department derives benefit and cost estimates for this proposed rule by comparing the baseline (the benefits and costs of the current part 30 regulation) with the benefits and costs of implementing the provisions in the proposed rule. Only the additional benefits and costs that are expected to be incurred due to the changes in this regulation are included in the analysis.

The Department sought to quantify and monetize the benefits and costs of the proposed rule where feasible. Where we were unable to quantify benefits and costs—for example, due to data limitations—we describe them qualitatively. This analysis covers a 10-year period (2026 through 2035) to ensure it captures major benefits and costs that accrue over time. In this analysis, we have sought to present benefits and costs both undiscounted and discounted at 7 and 3 percent, respectively.¹⁹

All costs from the proposed rule are incurred in the first year and total \$9.11 million. The 10-year monetized benefits of the proposed rule range from \$748.76 million to \$ 891.95 million (with 7 and 3 percent discounting, respectively). The annualized monetized benefits of the Final Rule are \$74.88 million (with 7 percent discounting) and \$89.19 million (with 3 percent discounting).

After considering both the quantified and non-quantified benefits of the proposed rule, the Department has concluded that the estimated benefits would justify the costs of the proposed rule. Below, we present an analysis of the costs and benefits of the proposed rule in the first year and over the 10-year analysis period.

The Department has examined this proposed rule and has determined that it is consistent with the policies and directives outlined in E.O. 14192, “Unleashing Prosperity Through Deregulation.” This rulemaking is

expected to be an E.O. 14192 deregulatory action.

A. Estimates of Sponsors Impacted by the Rule Across the 10-Year Period

The Department's analysis considers the expected benefits and costs of the changes to part 30. This analysis measures the costs and benefits as they accrue to sponsors and State partnering agencies. It is estimated that the number of sponsors will grow over time and our annual cost calculations reflect this growth. The Department based its estimate of the number of sponsors in each year using data from RAPIDS regarding the number of registered apprenticeship programs and based its estimate of the annual growth in registered apprenticeship programs on the average annual growth rate from FY2020 to 2024. The Department also used the same RAPIDS data to develop an estimate of the number of registered apprenticeship programs that have five or more apprentices in each year of the analysis.²⁰ While the Department expects that the number of registered apprentices will increase after part 30 is streamlined, we used prior data to estimate future growth because it is common practice in cost-benefit analysis, it is difficult to quantify how much the streamlining of part 30 will increase the growth of apprenticeship programs.²¹

This analysis primarily discusses how the first-year costs were calculated and indicates that the analysis repeats that calculation across the 10-year time frame using the appropriate number of sponsors in any given year. Exhibit 1 presents the estimated number of total active and new active program sponsors, and the estimated number total and new active sponsors with five or more apprentices projected for each year in the analysis.

EXHIBIT 1

Year	Total active sponsors	New sponsors	Total active sponsors with five or more apprentices	New sponsors with five or more apprentices
2026	29,969	1,781	7,902	401
2027	31,863	1,894	8,324	422
2028	33,877	2,014	8,768	444
2029	36,018	2,141	9,237	468
2030	38,294	2,276	9,730	493

¹⁹ Office of Management and Budget, Circular A–4, “Regulatory Analysis,” Sept. 17, 2003, <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>. As noted in E.O. 14192, “Unleashing Prosperity Through Deregulation,” on January 31, 2025, regulations should be consistent with the 2003 version of Circular A–4.

²⁰ The Department identified 26,512 total programs and 7,121 programs with five or more apprentices in RAPIDS as the starting point. The annual average growth rate for all programs was 6.32 percent and 5.34 percent for programs with five or more apprentices between FY2020 and FY2024. These data are used to estimate the projected number of total programs and those with

five or more apprentices for each year in the analysis.

²¹ The Department's cost-benefit analysis finds that the majority of the benefits from streamlining part 30 accrue to sponsors of registered apprenticeship programs. If the Department estimated a higher growth rate to registered apprenticeship, the estimated benefits of the proposed rule would be higher.

EXHIBIT 1—Continued

Year	Total active sponsors	New sponsors	Total active sponsors with five or more apprentices	New sponsors with five or more apprentices
2031	40,714	2,420	10,249	520
2032	43,287	2,573	10,797	547
2033	46,023	2,736	11,373	577
2034	48,932	2,909	11,980	607
2035	52,024	3,092	12,620	640

Benefits

The Department first presents the benefits that accrue under the proposed rule. Most of these benefits arise from cost-savings to the sponsors of registered apprenticeship programs because the proposed rule eliminates several requirements of the current part 30 regulations. The savings from eliminating these requirements are discussed in greater detail below.

In addition to the savings discussed below, there are several other benefits from streamlining the nondiscrimination requirements under part 30 that are not included in the Department's analysis. Under the proposed rule, sponsors will benefit from a more streamlined and less complex part 30 regulation, reducing confusion and the time required to answer questions or address confusion regarding compliance requirements. The proposed rule would also benefit sponsors by removing the legally questionable components of the current part 30 regulations, thereby eliminating legal risk that sponsors could be sued or legally challenged for actions taken to comply with part 30, such as setting utilization goals regarding the race or sex of program participants.

Since the proposed rule reduces the barriers for sponsors to create and operate registered apprenticeship programs, it may also lead to the registration of additional apprenticeship programs. The enhanced growth of registered apprenticeship programs could improve access for individuals to enroll in apprentices and receive high-quality job training—boosting their long-term earnings and having spill-over effects in the local economy. The increased proliferation of registered apprenticeship programs could also benefit local employers, as the creation of additional skilled apprentices could expand local talent pools and allow employers to more easily fill in-demand occupations.

Finally, chief among these benefits is the elimination of regulatory provisions that have the effect of encouraging the use of race- and gender-based

preferences in apprenticeship selection and advancement decisions. By removing these requirements, the proposed rule promotes a return to individual, merit-based evaluation, consistent with the principle that all Americans should be treated as individuals rather than as members of demographic groups. The Department believes this shift will strengthen public confidence in the fairness of the apprenticeship system, reduce legal uncertainty, and encourage broader participation by sponsors who may have been deterred by the prior rule's prescriptive and group-based mandates.

While these benefits could be substantial, the Department did not include these benefits in its analysis because of data limitations that raise concern about our ability to accurately quantify these benefits. Collectively however, these benefits reinforce the Department's conclusion that the advantages of this proposal outweigh any potential costs.

A. Eliminating One-Time Costs for Sponsors of New Registered Apprenticeship Programs

Under the current part 30 regulation, sponsors must post their equal opportunity pledge on bulletin boards and through electronic media, such that it is accessible to all apprentices and applicants to apprenticeship programs. This requirement imposes costs on sponsors operating a registered apprenticeship program for the first time, as they are required to take staff time to post this pledge. Under Title VII (42 U.S.C. 2000e–10) and the ADA (42 U.S.C. 12115), employers are already required to post a notice summarizing Federal laws prohibiting discrimination in employment. Removing this comparable requirement from part 30 would therefore lead to savings for new sponsors of registered apprenticeship programs without depriving apprentices of crucial information about their employment rights.

The Department assumes that new sponsors choose to put up a physical copy of the pledge and also post it on their website. The Department assumes

it takes a sponsor 5 minutes (0.08 hours) to post the pledge and that this task is performed by an administrative assistant. To calculate the hourly compensation rate, the Department used the median hourly wage rate for Secretaries and Administrative Assistants, Except Legal, Medical, and Executive (SOC code 43–6014) of \$22.26,²² and assumed a 17% overhead cost²³ and a 42-percent benefit cost.²⁴ The total hourly compensation rate is $[\$22.26 + (\$22.26 \times 42\%) + (\$22.26 \times 17\%)]$, or \$35.39. We multiplied the time estimate for this provision by the hourly compensation rate to obtain a total labor cost per sponsor of \$2.83 ($\$35.39 \times 0.08$). To estimate the materials cost, the Department assumed that the pledge is one page, and that the cost per page for photocopying is \$0.10, resulting in a materials cost of \$0.10 ($\$0.10 \times 1$) per sponsor. The total cost of putting up a physical copy of the pledge per sponsor is therefore \$2.93 ($\$2.83 + \$0.10$). Additionally, the Department also assumes it takes a sponsor 10 minutes (0.17 hours) to post the pledge on its website and that this task is performed by a web developer at an hourly compensation rate of \$69.51.²⁵ The cost of posting the pledge

²² BLS, “2024 National Occupation Employment and Wage Estimates for Secretaries and Administrative Assistants, Except Legal, Medical, and Executive (43–6014), Hourly median wage,” retrieved June 17, 2025, <https://www.bls.gov/oes/tables.htm>.

²³ Cody Rice, U.S. Environmental Protection Agency, “Wage Rates for Economic Analyses of the Toxics Release Inventory Program,” June 10, 2002, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0005>.

²⁴ Benefit cost is derived from the “Employer Costs for Employee Compensation Summary” for March 2025 release from BLS, available at <https://www.bls.gov/news.release/eccec.nr0.htm>. The total benefits value was compared to the wages and salary amount at the 50th wage percentile for private industry workers. This calculation, $\$9.79 + \$23.18$, produced a benefits cost of 42 percent of wages.

²⁵ Median wage for Web Developer (Occupation code: 15–1134) is \$52.47 (source: BLS, “National Occupation Employment and Wage Estimates by Ownership,” 2024, <http://www.bls.gov/oes/current/000001.htm#11-0000>). The fully adjusted wage rate for a web developer accounting for overhead and benefits is $43.72 + (43.72 \times 0.17) + (43.72 \times 0.42)$, which equals \$69.51.

on the sponsor's website is \$11.82 ($\$69.51 \times 0.17$). In total, the current provision requiring the posting of physical copy of the pledge and the posting of the pledge on the sponsor's website costs \$14.75 ($\$2.93 + \$11.82$) per new sponsor.

The Department estimates that there are 1,781 new sponsors in the first year (see Exhibit 1) that would incur these costs. Multiplying this sum (\$14.75) by the estimate of new sponsors (1,781) in the first year (2026) results in a cost-benefit of \$26,270 from eliminating this provision. Looking over the full ten-year period, the annualized savings from eliminating the cost of posting the EEO pledge are \$25,534 (with 7 percent discounting) and \$30,430 (with 3 percent discounting).

B. Eliminating On-Going Costs for All Sponsors

The current part 30 regulations also require that each sponsor conduct orientation and periodic information sessions for apprentices, journeyworkers who directly supervise apprentices, and other individuals connected with the administration or operation of the sponsor's apprenticeship program to inform and remind such individuals of the sponsor's equal employment opportunity policy with regard to apprenticeship (current § 30.3(b)(2)(iii)). Under current § 30.3(b)(4)(i), sponsors are also required to provide anti-harassment training, which we assume are incorporated into periodic orientation and information sessions. This training must include active participation by trainees, such as attending a training session in person or completing an interactive training online and includes, at a minimum, communications to apprentices and journeyworkers who directly supervise apprentices that harassing conduct will not be tolerated, the definition of harassment and types of conduct that constitute harassment, and the right to file a harassment complaint.

Using data from RAPIDS, the Department calculated that there are on average 25.4 apprentices per sponsor, so we round down to 25 apprentices per program.²⁶ The Department further assumes a one-to-one ratio between an apprentice and journeyworker in estimating the cost of orientations and periodic information sessions. The Department first estimated that the 29,969 programs in the first year (2026) will hold one 45-minute regular orientation and information session with an average of 25 apprentices

(\$33.39 per hour)²⁷ and 25 journeyworkers (\$52.47 per hour)²⁸ per sponsor. The Department estimated that a human resource manager (\$107.04)²⁹ will need to spend 2 hours to develop and prepare written materials for the session in the first year, and 2 hours to cover maintaining the training materials that were already saved on the computer in subsequent years.

This calculation results in a total cost-saving benefit for removing this provision of approximately \$54.66 million in the first year (2026). It is assumed that all sponsors would hold one 45-minute regular orientation and information session annually if this requirement was not eliminated by the rule. This calculation is therefore repeated in subsequent years. The annualized savings from the elimination of this cost ranges from \$53.13 million (with 7 percent discounting) to \$63.31 million (with 3 percent discounting).

Additionally, under the current part 30, all sponsors are required to reach out to a variety of recruitment sources, including organizations that serve individuals with disabilities, to ensure universal recruitment (current § 30.3(b)(3)). Sponsors are required to develop a list of recruitment sources that generate referrals of women, minorities, and persons with disabilities with contact information for each source. Further, sponsors are required to notify these sources in advance of any apprenticeship opportunities and while a firm deadline is not set, the part 30 regulations suggest 30 days' notice if possible. This current outreach protocol may lead employers to incur costs due to the additional delay in the hiring process resulting from this rule. The Department, however, does not have enough information to estimate the potential costs sponsors currently incur from these delays.

²⁷ We calculated the hourly compensation rate for an apprentice by multiplying the average hourly wage of \$21.00 (as published by ZipRecruiter, last updated June 16, 2025, <https://www.ziprecruiter.com/Salaries/Apprenticeship-Salary>) by 1.59 to account for private-sector employee benefits and overhead. Thus, the hourly compensation rate for an apprentice is \$33.39 ($\$21.00 \times 1.59$).

²⁸ We calculated the hourly compensation rate for a journeyworker by multiplying the average hourly wage of \$33.00 (as published by ZipRecruiter, last updated June 16, 2025, <https://www.ziprecruiter.com/Salaries/Journeyman-Salary>) by 1.59 to account for private-sector employee benefits and overhead. Thus, the hourly compensation rate for a journeyworker is \$52.47 ($\$33.00 \times 1.59$).

²⁹ We calculated the hourly compensation rate for a human resource manager (Occupation code 11-3121) by multiplying the median hourly wage of \$67.32 by 1.59 to account for private-sector employee benefits and overhead. Thus, the hourly compensation rate for a human resource manager is \$107.04 ($\$67.32 \times 1.59$).

The kinds of activities sponsors engage in to satisfy this requirement include distributing announcements and flyers detailing job prospects, holding seminars, and visiting some of the sources who are likely able to provide access to designated groups. The Department assumed that the cost to sponsors to distribute information to designated groups will be the labor cost to comply with this provision. We also assumed that the activity to satisfy this provision will be performed by a human resource manager and an administrative assistant with hourly compensation rates of \$107.04 and \$35.39, respectively. We assumed this task takes 30 minutes (0.5 hour) of a human resource manager's time and 30 minutes (0.5 hour) of an administrative assistant's time per targeted source. We calculated the cost of this provision per affected sponsor by multiplying the time each staff member devotes to this task by their associated hourly compensation rates. We then multiplied the total labor cost by the assumed number of outreach sources (5) and by the total number of sponsors. All sponsors are assumed to conduct this outreach in all years. The resulting savings from eliminating this outreach provision are therefore \$10.67 million in the first year, with an annualized savings from the elimination of this cost for sponsors ranging from \$10.37 million (with 7 percent discounting) to \$12.36 million (with 3 percent discounting).

C. Savings From Eliminating Costs of Performing Utilization and Workforce Analysis Costs for Sponsors With Five or More Apprentices

The current part 30 regulations require sponsors with five or more apprentices to establish utilization goals for women and minorities (current §§ 30.5 through 30.7). First, sponsors conduct a workforce analysis to identify the racial, sex, and ethnic composition of their apprentices. Second, an availability analysis will establish a benchmark against which the existing composition of apprentices will be compared. Sponsors establish utilization goals and engage in targeted outreach, recruitment, and retention efforts when the sponsor's utilization of women, Hispanics or Latinos, or individuals in racial minority groups are "significantly less than would be reasonably expected given the availability of such individuals for apprenticeship." Registration Agencies work closely with sponsors during compliance reviews to assist in the development of an availability analysis and setting or reassessing utilization goals for race, sex, and ethnicity. The

²⁶ This estimate is from RAPIDS data at the end of FY2024.

Department also provides a data tool to assist in the collection and analysis of relevant demographic data for the purposes of goal setting.

The Department has determined that eliminating the utilization goal requirement will create three types of cost-savings benefits: Savings from the elimination of costs associated with the familiarization with the data tool for new sponsors, savings from the elimination of costs associated with the workforce analysis, and savings from the elimination of costs associated with the utilization analysis.

To quantify the savings from the elimination of costs associated with new sponsors' familiarization with the data tool, the Department assumes that new sponsors with five or more apprentices (401 in 2026) will incur one hour of HR manager labor (\$107.04 per hour) to familiarize the organization with the tool. This is estimated to create \$42,876 in savings from the elimination of these tool familiarization costs in the first year of 2026. We repeated this calculation for the following years. Removing the utilization goal requirement from part 30 therefore creates an annualized savings of \$40,004 (with 7 percent discounting) and \$47,537 (with 3 percent discounting) from the elimination of new sponsors' tool familiarization costs.

To calculate the savings from removing the workforce analysis requirements from part 30, the Department determined that the methodology for conducting workforce analyses under the current part 30 results in 2 hours of HR manager labor (\$107.04 per hour) for all sponsors with five or more apprentices (7,902 in 2026). Under the current part 30 regulations, all sponsors with five or more apprentices must conduct workforce analysis every 2.5 years. In calculating the savings for each year, the Department divided the number of applicable sponsors in each year by 2.5 to reflect the assumption that sponsors would have conducted the analysis per the 2.5-year timeline. This means that in any given year 40 percent of these sponsors would have conducted the workforce analysis or that it would have taken 2.5 years to have these sponsors conduct new workforce analyses. The cost-savings from eliminating the requirement to conduct workforce analyses in the first year is therefore \$676,642 ($7,902 \times 0.4 \times \$107.04 \times 2$ hours). We repeated this calculation for the following years using the appropriate number of sponsors in any given year, resulting in an annualized savings from the removal of the workforce analysis requirement of

\$631,313 (with 7 percent discounting) and \$750,187 (with 3 percent discounting) for sponsors.

To calculate the savings from the removal of the utilization analysis requirement, the Department determined that the utilization analysis results in 0.5 hour of HR manager time (\$107.04 per hour) for all sponsors with five or more apprentices (7,902 in 2026) every 5 years. The cost-savings from removing the requirement to conduct utilization analyses in the first year is \$84,580 ($0.5 \text{ hour} \times \$107.04 \times (7,902/5 \text{ years})$). We repeated this calculation for the following years, and the savings to sponsors from not having to conduct utilization analyses has an annualized benefit of \$78,914 (with 7 percent discounting) and \$93,773 (with 3 percent discounting) for sponsors.

In addition to the normal outreach, recruitment, and retention activities required of all sponsors under current part § 30.3(b), the current part 30 regulations require a sponsor of an apprenticeship program, whose utilization analyses revealed underutilization of a particular designated group or groups of individuals pursuant to current § 30.6 and/or who has determined pursuant to current § 30.7(e) that there are impediments to EEO for individuals with disabilities, to engage in targeted outreach, and retention for all underutilized groups in current § 30.8. We assumed that this additional outreach happens in the same manner as the universal outreach discussed above.

We assumed that the current cost to sponsors to distribute information about apprenticeship opportunities to organizations serving individuals with disabilities is the labor cost. We also assumed that the labor for this provision will be performed by a human resource manager and an administrative assistant with hourly compensation rates of \$107.04 and \$35.39, respectively. The Department estimated that this dissemination task takes 30 minutes (0.5 hour) of a human resource manager's time and 30 minutes (0.5 hour) of an administrative assistant's time per targeted source. The cost of the current provision per affected sponsor is the time each staff member devotes to this task multiplied by their associated hourly compensation rates. This calculation resulted in a labor cost of \$71.22 ($(\$107.04 \times 0.5) + (\$35.39 \times 0.5)$) per source.

We estimated that the number of sponsors who need to engage in targeted outreach and recruitment for at least one relevant demographic group is 95 percent of the total sponsors with five

or more apprentices. We understand this is likely an over-estimate of the number of sponsors that must conduct this outreach, as more than 5 percent of sponsors may meet their utilization goal for all demographic groups and may not have to conduct outreach, however the Department does not have complete or reliable data to produce an alternative estimate. We then multiplied this total labor cost by the share of sponsors with five or more apprentices (7,902), the share of sponsors that undertake a utilization analysis in any given year (20 percent³⁰) and the share of sponsors that are estimated to identify underutilization and/or problem areas in one or more of the relevant demographic groups—(95 percent). This calculation ($\$71.22 \times 7,902 \times 0.20 \times 0.95$) results in a total cost of the current outreach provision of approximately \$106,928 in 2026. The benefit from eliminating this requirement is equal to these estimated costs since sponsors will no longer need to conduct this outreach. We repeated this calculation for the following years using the appropriate number of sponsors in any given year. The annualized savings to sponsors from not having to conduct this additional outreach ranges from \$99,755 (with 7 percent discounting) to \$118,538 (with 3 percent discounting).

D. Savings From Eliminating Affirmative Action Program Review Costs for Sponsors With Five or More Apprentices

Affirmative action program reviews in the current part 30 regulations result in three additional costs for sponsors: personnel process reviews, written affirmative action plan updates during compliance reviews, and written affirmative action plan updates within three years of compliance reviews (estimated to occur 2.5 years later in this analysis). The current part 30 requires sponsors with five or more apprentices to review personnel processes annually (§ 30.9). The Department estimated the current costs of each of these components and summed them to estimate the savings to sponsors from eliminating affirmative action program reviews.

To calculate the current costs imposed on sponsors from personnel process reviews, the Department calculated the cost for all sponsors in 2026 with five or more apprentices (7,902) to spend 8 hours of HR manager labor (\$107.04 per hour) conducting the

³⁰ This is the percentage of sponsors that undergo compliance review each year, as determined by the 5-year schedule on which sponsors undergo compliance reviews.

review. This provision is estimated to result in an undiscounted cost of \$6.77 million in 2026 ($7,902 \times 8 \text{ hours} \times \$107.04$).

To determine the current cost of the written affirmative action plan update at the time of the compliance review, the Department calculated the cost for all sponsors in 2026 with five or more apprentices (7,902) to spend 12 hours³¹ of HR manager labor every 5 years at the time of the compliance review. With the existing compliance review rate at 20 percent, this means that approximately one in five of these sponsors undergo a compliance review every year. This provision currently results in an undiscounted cost of approximately \$2.03 million in 2026 ($7,902 \times 12 \text{ hours} \times (1 \div 5) \times \$107.04$).

To determine the cost of the written affirmative action plan update within three years of the compliance review, the Department calculated the cost for all sponsors in 2026 with five or more apprentices (7,902) to spend 6 hours³² (estimated to be less because of the lesser workload from not overlapping with the compliance review) of HR manager time every 5 years. This provision results in an undiscounted cost of \$1.01 million in 2026 ($7,902 \times 6 \text{ hours} \times (1/5) \times \$107.04$). We repeated this calculation for the following years using the appropriate number of sponsors in any given year.

The total cost of the current affirmative action plan program provision, and therefore the savings from it being eliminated, is approximately \$9.8 in 2026 ($6.77 \text{ million} + \$2.03 \text{ million} + \$1.01 \text{ million}$). The annualized savings from eliminating affirmative action program reviews ranges from \$9.15 million to \$10.88 million at 7 percent and 3 percent, respectively.

E. Invitation To Self-Identify as an Individual With a Disability

The current part 30 regulations under § 30.11 require sponsors with five or more apprentices to invite applicants for

apprenticeship to voluntarily self-identify as an individual with a disability protected by this part at two stages: (1) At the time they apply or are considered for apprenticeship; and (2) after they are accepted into the apprenticeship program but before they begin their apprenticeship. Each year, all sponsors with five or more apprentices are required to administer the invitation to self-identify twice: Once to all applicants prior to the offer of apprenticeship, and once after the offer of apprenticeship to those who were extended offers. The Department estimated that sponsors post 42 positions in 2026 and receive 15 applicants per posting.³³ Of those positions, the Department estimated that 42 offers of enrollment are made and 42 apprentices choose to enroll in 2026. The Department estimated that it would take an apprentice (\$33.39 per hour) 5 minutes (0.08 hours) to complete the form. Furthermore, an administrative assistant (\$35.39 per hour) would need to spend 0.5 hour annually to record and keep the forms. As a result, this requirement has an undiscounted cost in 2026 of \$1.42 million ($7,902 \times ((15 \text{ applications} \times 42 \text{ job listings} \times .08) + (42 \text{ offers of apprenticeship} \times .08)) \times \$35.39 + 7,902 \times 0.5 \times \$35.39$). For the 10-year analysis period, this provision has an annualized cost of \$1.33 million and \$1.58 million (at 7 percent and 3 percent discounting, respectively).³⁴ In addition, sponsors with five or more apprentices are required to remind apprentices yearly that they can update their invitation to self-identify. The Department assumed that these sponsors send out an annual reminder email at the cost of \$22,372 ($7,902 \times 0.08 \text{ hour} \times \$35.39$). We repeated this calculation for each remaining year in the analysis period using the estimated number of sponsors for each year. This provision in total has an annualized cost of \$20,873 and \$24,803 (at 7 percent and 3 percent discounting, respectively).

Costs

Below, the Department presents the costs incurred on relevant stakeholders, mainly program sponsors and SAAs, from this proposed rule. These costs are broken into two major categories: costs to sponsors of familiarizing themselves

with the regulatory change, and the cost to SAAs. These two main costs of the proposed rules and other provisions of the proposed rule the Department found to have minimal to no costs compared to the current part 30 are discussed below. This provision in total has an annualized cost of \$20,873 and \$24,803 (at 7 percent and 3 percent discounting respectively).

A. Familiarization With Regulatory Change

To estimate the cost of initial rule familiarization, we multiplied the number of apprenticeship sponsors in 2026 (26,512)—the first full year in which the change will be in effect—by the amount of time required to read the new rule (1 hour) and by the average hourly compensation of a private-sector human resources manager (\$107.04). This cost is only incurred in the first year of the change, so the total cost to sponsors for time spent on familiarization amounts is approximately \$3.21 million in labor costs. There are no familiarization costs for future years because sponsors will already be complying with nondiscrimination laws.

B. Updating Standards for Compliance

Pre-existing sponsors of registered apprenticeship programs will also need to develop language or make adjustments and updates to existing standards to comply with the proposed changes to part 30. This will be a one-time cost only imposed on pre-existing sponsors that already had standards prior to the publication of final rule. The Department estimates that updating standards to comply with part 30 will mainly be removing items currently required by part 30 and therefore estimates the burden will be minimal. Accordingly, the Department estimates the average response time for the projected 28,188 pre-existing apprenticeship programs in FY2026 to ensure standards comply with part 30 is 20 minutes (0.33 hours).³⁵ The estimated annual burden is 9,301 hours ($28,188 \times 0.33$). The Department assumes the standards will be updated by an administrative assistant. Therefore, the Department estimates that the annualized cost is \$329,194 ($9,301 \times \$35.39$).

Registration agency staff are responsible for reviewing and providing input on a sponsor's apprenticeship program standards to ensure compliance with the requirements in part 30.

³¹ A workforce analysis (1); a utilization analysis (2); goal-setting (if necessary) (3); and a full update of the written affirmative action plan (4) need to be undertaken at the compliance review. Because we have already costed out (1), (2), and (3), the sponsor would need additional 12 hours to fully update the written affirmative action plan.

³² A written affirmative action program review within three years of compliance reviews contains (1) workforce analysis and (2) updating the written affirmative action plan to include the updated workforce analysis and a description of the review of personnel practices and any changes made as a result of that review (see 30.9(b)). Because we have already costed out (1), the 6 hours are for including updated the workforce analysis and a description of the review of personnel practices and any changes made as a result of that review (see current 30.9(b)).

³³ The Department determined the number of positions posted from conversations with programs of various sizes. We determined that the largest, statewide programs post more than 15 jobs, but the Department used this as an average for all apprentices to avoid under-estimating the costs.

³⁴ It is assumed that there will be 100 percent participation in the invitation to self-identify and therefore, the cost of this provision is likely overestimated.

³⁵ There are 28,188 pre-existing sponsors in FY2026 because there are 29,969 projected sponsors in FY2026 and 1,781 of these sponsors are new. ($29,969 - 1,781 = 28,188$).

Registration agencies will therefore incur a one-time cost to review updated standards for pre-existing programs. The Department estimates that the review and input provided by registration agency staff for program sponsors will take 10 minutes, which results in 4,792 annual burden hours ($28,188 \times 0.17$ hours). Using the State employee wage calculated above, the total cost to registration agency of this one-time review is \$412,342 ($4,792 \text{ hours} \times \$86.05$).

C. Revision of State Plan

The process of updating a State equal opportunity plan may potentially involve various different people at different stages of implementation. Updating the plan will include drafting the new plan, ensuring conformity and that State laws and practices do not exceeding the proposed rule, and completing all administrative procedures that may apply, such as revisions to a State's apprenticeship law or policy that may require a public notice and comment period, training for

SAA staff on the revised State plan, and outreach to program sponsors to inform them of the relevant aspects of the revised State plan once it has been approved by the Department. The updates to State equal opportunity plans include changing language and existing requirements such that they align with the regulatory changes herein. To calculate the costs, the Department assumed that the process to revise the State plan will take a full year of effort (2,080 hours) to complete.³⁶ This is the Department's best estimate for updating the existing State plan. For simplicity, we assumed that an SAA human resource manager will complete the task at an hourly compensation rate of \$86.05.³⁷ This amounts to a one-time cost of \$5.9 million in the first year ($2,080 \text{ hours} \times \$86.05 \times 33 \text{ SSA States}$).³⁸ *Complaint Referral Procedures* § 30.4 within the proposed rule directs the Registration agencies to refer complainants alleging illegal discrimination to the appropriate enforcement agency. Since the complaint process is not a new process,

the Department does not expect that these provisions will add significantly to the burden on Registration Agencies as these agencies are currently required to refer complaints to other EEO agencies under current § 30.14(c)(3).

D. Adopting Uniform Procedures Under 29 CFR Parts 29 and 30 for Deregistration, Derecognition, and Hearings

The proposed rule generally aligns part 30 with part 29 procedures for deregistration of apprenticeship programs, derecognition of SAAs, and hearings (§§ 30.6 through 30.7). These provisions are not expected to impose a burden because SAAs are already following these procedures in part 29.

Summary of Cost-Benefit Analysis

Exhibit 2 presents a summary of the first-year benefits and costs of the proposed rule, as described above. As shown in the exhibit, the total first-year benefit of the proposed rule is \$77.51 million and the total first year costs are \$9.86 million.

EXHIBIT 2

Provision	Entity affected	Monetized costs (\$ million)
No longer posting equal opportunity pledge	Sponsor	– 0.03
No longer conducting universal outreach	Sponsor	– 10.67
No longer conducting EO training	Sponsor/Apprentice	– 54.66
No longer conducting Utilization and Workforce Analysis	Sponsor	– 0.80
No longer Conducting Affirmative Action Program Reviews	Sponsor	– 9.81
No longer providing an invitation to Self-Identify as an individual with a disability	Sponsor/Apprentice	– 1.45
Familiarization with Regulatory Change	Sponsor	3.21
Revision of State Equal Opportunity Plan	SSA	5.91
Updating Standards to Align with Revised Part 30 Regulation	Sponsor/Registration Agencies	0.74
Total First-Year Costs		– 67.57

Exhibit 3 presents a summary of the monetized costs and benefits associated with the final rule over the 10-year analysis period. The monetized costs

and benefits displayed are the yearly summations of the calculations described above. Costs and benefits are presented as undiscounted 10-year

totals, and as present values with 7 and 3 percent discount rates.

EXHIBIT 3

Year	Monetized benefit (\$million/year)	Monetized cost (\$million/year)
2026	77.53	9.86
2027	82.31	

³⁶ Note that this calculation is only the administrative costs of updating the State EEO plan, as opposed to the costs of implementing the new plan, or any new burdens on State Agencies. Since the updated State plan for non-discrimination in apprenticeship should reflect the Federal regulations, these costs should be accounted for and addressed elsewhere in the analysis under discussions of costs.

³⁷ We calculated the hourly compensation rate for a human resource manager at a State agency by multiplying the hourly wage of \$48.07 (GS–13 step 5) by 1.62 for public sector employee benefits

(source: BLS, “National Compensation Survey, Employer Costs for Employee Compensation,” <https://www.bls.gov/ecec/data.htm> (last visited May 27, 2025)). For State and local government workers, wages and salaries averaged \$38.45 per hour worked in 2024, while benefit costs averaged \$23.81, which is a benefits rate of 62 percent) and 1.17 to account for overhead costs (source: Cody Rice, U.S. Environmental Protection Agency, “Wage Rates for Economic Analyses of the Toxics Release Inventory Program,” June 10, 2002, <https://www.regulations.gov/document/EPA-HQ-OPPT-2014-0650-0005> (last visited May 27, 2025)) to

account for state and local employee benefits. The hourly compensation rate for a human resource manager at a State agency is thus \$86.05 ($(\$48.07 \times 1.17) + (\$48.07 \times 1.62)$).

³⁸ The estimated time to complete the revisions is 12 months (2,080 hours). The calculation used the hourly compensation rate for a state human resource manager (\$86.05) multiplied by 2,080 (the assumed number of work hours in a year) and by the total number of State Apprenticeship Agencies (33) to obtain the total cost. This cost only accrues in the first year of the ten-year analysis period.

EXHIBIT 3—Continued

Year	Monetized benefit (\$million/year)	Monetized cost (\$million/year)
2028	87.39	
2029	92.78	
2030	98.50	
2031	104.58	
2032	111.03	
2033	117.89	
2034	125.17	
2035	132.90	
Undiscounted	1,030.06	9.86
7% Discounted	748.76	9.86
3% Discounted	891.95	9.86
Annualized 7%	74.88	0.99
Annualized 3%	89.19	0.99

As mentioned above, due to data limitations, the Department did not quantify several important benefits to society provided by the proposed rule. The proposed rule is expected to result in several overarching benefits to apprenticeship programs and specific benefits resulting from a less legally ambiguous, and more streamlined rule. The proposed rule will reduce barriers to register and operate a registered apprenticeship program, allowing the creation of additional programs that allow more individuals to receive training and benefiting businesses in meeting their skills needs.

Regulatory Alternatives

In addition to the proposed rule, the Department has considered three regulatory alternatives: (a) Repeal Part 30 entirely; (b) Only eliminate the additional affirmative action requirements pertaining to sponsors with five or more apprentices while retaining the remainder of the 2016 final rule; (c) Take no action, that is, to leave the 2016 final rule intact.

The Department conducted economic analyses of the three alternatives to better understand their costs and benefits and the implied tradeoffs (in terms of the costs and benefits that would be realized) relative to the proposed rule. Below is a discussion of each alternative along with an estimation of their costs and benefits. All costs and benefits use the 2016 final rule as the baseline for the analysis.

A. Repeal Part 30 Entirely

This alternative yields many of the same benefits as the proposed rule but would also remove the cost to Registration Agencies (the Department of Labor's Office of Apprenticeship (OA) or SAAs) related to the referral of complaints, leading to additional cost-saving benefits.

The Department assumed that, when a Registration Agency receives a complaint, it takes 15 minutes (0.25 hours) for a public-sector human resource manager (86.05 per hour) to refer the complaint to the correct entity. The Department estimates that 421 apprentices file a complaint in the first year and the number of complaints rises by 9 percent each year.³⁹ Based on this assumption, the Department estimated that the savings to registration agencies from not having to refer complaints is \$36,227 in the first year. The Department estimates that this has an annualized savings benefit of \$39,413 and \$47,337 (at 7 percent and 3 percent discounting, respectively).

The Department assumes sponsors would still have to refer complaints to the relevant agencies that oversee nondiscrimination laws to comply with those laws and therefore would receive minimal to no cost savings from not having to refer these complaints to the registration agency as well.

Additionally, removing part 30 would remove the costs associated with deregistering programs and derecognizing SAA that are violating part 30. However, as mentioned in the preamble, the Department is unaware of any instance in which a program or an SAA has been deregistered or

derecognized because of failure to comply with part 30 (current § 30.15, § 30.16, and § 30.18(d)). The Department therefore assumes that removing the deregistration or derecognition components of the current part 30 rule would create minimal to no cost savings. The benefits of this alternative would therefore be the same in each year as the proposed rule, with additional cost-savings from the elimination of referral requirements.

In estimating costs, the Department believes that the elimination of part 30 entirely would remove conformity across the registered apprenticeship system by creating an inconsistent regulatory framework across states. If some states left their current apprenticeship affirmative action laws in place, it would be harder for sponsors to navigate and comply with this system. This lack of conformity would therefore create confusion and hinder the deregulatory goals of the rulemaking from being achieved on a nationwide basis. Additionally, if some states retained the use of race- and gender-based preferences in apprenticeship selection and advancement decisions, the apprenticeship system in these states would continue to conflict with the merit-based principles that the apprenticeship system, and overall American workforce, should represent.

While the Department believes these costs from a lack of conformity and conflict with merit principles could be substantial, these costs are largely intangible and would be difficult to estimate. As a result, the Department estimates that the only monetized costs would be the one-time cost of removing references to Part 30 in apprenticeship program standards, which was estimated to be \$741,536, due to data and other limitations referenced above, there would be no quantifiable costs to repealing part 30 entirely because states

³⁹ The EEOC reports that there were 88,531 charges in FY2024 and that the number of complaints between FY2023 to FY2024 rose by 9.22% (Source: Enforcement and Litigation Statistics, EEOC. Accessed June 20, 2025. <https://www.eeoc.gov/data/enforcement-and-litigation-statistics-0>). Based on this growth rate, we estimate there will be 105,184 complaints in 2026. We assume apprentices file the same percentage of complaints as their share of the workforce. We understand this may be an over or underestimate as apprentices may be less or more likely to file complaints than the broader workforce. Since apprentices make up 0.4% of the workforce, we assumed that they file 421 complaints a year (105,184 × 0.4%). We repeat this calculation each year to account for the growth in complaints each year.

would not have to submit updated State plans and sponsors would not need to familiarize themselves with the rule

change. Exhibit 4 presents a summary of the monetized costs of this alternative option over the 10-year analysis period.

Costs are presented as undiscounted 10-year totals, and as present values, using 7 percent and 3 percent discount rates.

EXHIBIT 4

Year	Monetized benefit (\$million/year)	Monetized cost (\$million/year)
2026	77.57	0.74
2027	82.35	0.00
2028	87.43	0.00
2029	92.82	0.00
2030	98.55	0.00
2031	104.63	0.00
2032	111.09	0.00
2033	117.95	0.00
2034	125.24	0.00
2035	132.98	0.00
Undiscounted	1,030.61	0.74
7% Discounted	749.15	0.74
3% Discounted	892.42	0.74
Annualized 7%	74.88	0.07
Annualized 3%	89.24	0.07

B. Only Remove Additional Requirements Pertaining to Programs With Five or More Apprentices

This alternative yields only the cost-savings that come from eliminating the provisions under the current part 30 that require sponsors with five or more apprentices to take additional affirmative action steps. This more limited change would therefore eliminate the following costs: new sponsors' familiarization with apprenticeship utilization data tool, cost of the workforce analysis, cost of the utilization analysis, the additional dissemination of resources for designated demographic groups if a sponsor is found to be underutilizing said group, costs related to Affirmative Action Program reviews, and the cost of

inviting apprentices to self-identify as an individual with a disability (as well as sending email reminders about this self-identification). Sponsors would still incur the costs of orientation and information sessions and universal outreach. New sponsors would also continue to incur the cost of posting EEO pledges.

Under this alternative, the Department assumes that sponsors would still incur the same rule familiarization costs and SSAs would still have to submit revised State plans under current § 30.18. Only pre-existing programs with five or more apprentices would incur costs from updating standards. The Department estimates that there will be 7,501 pre-existing programs with more than 5 apprentices

in FY2026.⁴⁰ Based on the methodology described above, we estimated sponsors with five or more apprentices will incur \$87,605 from the cost of updating standards and registration agencies will incur \$109,732 in costs from reviewing updated standards, for a total cost of \$197,337 of updating standard for programs with five or more apprentices. This cost is lower because fewer sponsors (*i.e.*, only those with five or more apprentices) would need to update standards. The total cost of this option is therefore \$9.31 million.

Exhibit 5 presents a summary of the monetized costs of this alternative option over the 10-year analysis period. Costs are presented as undiscounted 10-year totals, and as present values, using 7 percent and 3 percent discount rates.

EXHIBIT 5

Year	Monetized benefit (\$million/year)	Monetized cost (\$million/year)
2026	12.17	9.31
2027	12.82	
2028	13.50	
2029	14.22	
2030	14.98	
2031	15.78	
2032	16.63	
2033	17.52	
2034	18.45	
2035	19.44	

⁴⁰ There were estimated to be 7,902 sponsors with five or more apprentices in total in FY2026, 401 of which would be new sponsors. Subtracting new programs, it is estimated that there will be 7,501 pre-existing sponsors with five or more apprentices in FY2026.

EXHIBIT 5—Continued

Year	Monetized benefit (\$million/year)	Monetized cost (\$million/year)
Undiscounted	155.52	9.31
7% Discounted	113.54	9.31
3% Discounted	134.92	9.31
Annualized 7%	11.35	0.93
Annualized 3%	13.49	0.93

C. Take No Action

This alternative yields no additional costs or benefits to society because it does not deviate from the baseline, that is, the 2016 final rule. However, the Department notes that taking no action would prevent the benefits that would accrue from this proposed rule. In addition to decreasing the burden on sponsors and registration agencies, chief among the benefits from the proposed rule is the elimination of regulatory provisions that have the effect of encouraging the use of race- and gender-based preferences in apprenticeship selection and advancement decisions. By removing these requirements, the proposed rule promotes a return to individual, merit-based evaluation, consistent with the principle that all Americans should be treated as individuals rather than as members of demographic groups. Without this change, the Department believes the public's confidence in the fairness of the apprenticeship system could be undermined, that legal uncertainty would remain for current sponsors, and that prospective sponsors may be deterred by the prior rule's prescriptive and group-based mandates.

B. Regulatory Flexibility Act, Small Business Regulatory Enforcement Fairness Act of 1996, and Executive Order 13272 (Proper Consideration of Small Entities in Agency Rulemaking)

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601 *et seq.*, as amended by Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121 (Mar. 29, 1996), hereafter jointly referred to as the RFA, requires agencies to prepare an initial regulatory flexibility analysis (IRFA) when proposing, and a final regulatory flexibility analysis (FRFA) when issuing, regulations that will have a significant economic impact on a substantial number of small entities.

The Department conducted the analysis below of the burden on small entities from the proposed rule and, based on that analysis, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

1. Why Action Is Being Considered

The Department has determined that the proposed deregulatory action is necessary to remove administrative barriers to participation in registered apprenticeship. As described throughout the preamble for this NPRM, in the Department's view, the proposed changes to the regulation at 29 CFR part 30 would significantly reduce administrative burdens for existing registered apprenticeship sponsors, and could alleviate concerns expressed by employers (including small businesses) regarding the amount of administrative burden they would have to take on to participate in registered apprenticeship. The Department is considering this deregulatory action because these outcomes would help accelerate the expansion of registered apprenticeship, in line with the Administration and the Department's ambitious goals to grow the system, including in industries and sectors where registered apprenticeship is not currently widespread. In addition, the Department is considering this deregulatory action in light of the Administration's call for Federal agencies to review their regulations and remove regulations that impose undue or unnecessary burdens on stakeholders.

2. Objectives of, and Legal Basis for, the Proposed Rule

The primary objective of the proposed rule is to alleviate administrative burden for registered apprenticeship stakeholders and promote a more straightforward framework for the regulated community to participate in the system and maintain compliance with the governing regulations (at 29 CFR parts 29 and 30). In addition, this proposed rule seeks to eliminate a duplicative and ineffective (and, in light of recent case law, legally questionable) regulatory framework for antidiscrimination protections in registered apprenticeship. These objectives align with the broader goals of the Administration and the Department to identify and modify burdensome regulations, preserve limited enforcement resources, and keep pace with evolving issues in antidiscrimination law. The National

Apprenticeship Act of 1937 stands as the Department's statutory basis for promulgating regulations on apprenticeship.

3. Classes of Small Entities

A small entity is one that is independently owned and operated and that is not dominant in its field of operation. 5 U.S.C. 601(3); 15 U.S.C. 632. The definition of small entity varies from industry to industry to properly reflect industry size differences. 13 CFR 121.201. An agency must either use the SBA definition for a small entity or establish an alternative definition for the industry. Using SBA size standards, the Department has conducted a small entity impact analysis on small entities in the five industry categories with the most registered apprenticeship programs and for which data were available: Construction, Educational Services, Manufacturing, Other Services, and Healthcare.⁴¹ These top five industry categories account for 57 percent of the total number of apprenticeship sponsors who had active apprenticeships in FY 2018.⁴²

One industry, Public Administration, made the initial top-five list but is not included in this analysis because no data on the revenue of small local jurisdictions were available. Local jurisdictions are classified as small when their population is less than 50,000. 5 U.S.C. 601(5).

Registered apprenticeship program sponsors may be employers, employer associations, industry associations, or labor management organizations and, thus, may represent businesses, multiple businesses, and not-for-profit organizations. The requirements of the

⁴¹ According to RAPIDS, the percent of programs (of all sizes) in the selected sectors in 2024 were as follows: Construction, 33.5 percent; Educational Services, 24.1 percent; Manufacturing, 4.3 percent; Other Services, 3.7 percent; Health Care and Social Assistance, 3.6 percent. Public Administration was 24.1 percent and 11.6 percent of programs did not have an industry available.

⁴² RAPIDS includes a portion of all registered apprenticeship programs and apprentices nationwide because SAAs that are recognized by the Department of Labor to serve as the Registration Agency may choose, but are not required, to participate in RAPIDS.

proposed rule, however, fall on the sponsor, and therefore we used sponsor data to create industry breakdowns.

4. Impact on Small Entities

The Department has estimated the incremental costs for small entities from the baseline of the 2016 Final Rule.⁴³ This analysis reflects the incremental cost of the proposed rule, as it adds to the requirements of the 2016 Final Rule. Using available data, we have estimated the costs to sponsors of familiarizing themselves with the rule change. A significant economic burden results when the total incremental annual cost as a percentage of total average annual revenue is equal to or exceeds 3 percent.⁴⁴ Because the estimated annual burden of the proposed rule is less than 1 percent of the average annual revenue of each industry category, the proposed rule is not expected to cause a significant economic impact to small entities. These entities include individual employers, groups of employers, labor management organizations, or industry associations that sponsor apprenticeships. As explained in detail below, the total impact amounts to approximately \$118.89 per affected small entity in the first year. All costs are incurred in the first year. Because all the proposed rule provisions will have a similar impact on entities across economic sectors, we calculated impacts to a representative single entity.⁴⁵

Costs

a. Familiarization With Regulatory Change

During the first year after implementation of the eventual final

rule, sponsors will need to learn about the new regulatory requirements. We estimated this cost for a hypothetical small entity by multiplying the time required to read the new rule (1 hours) by the average hourly compensation rate of a human resources manager (\$107.04, as calculated above). Thus, the resulting cost per small entity is 107.04 (\$107.04 × 1). This cost occurs only in the year after the final rule is published.

b. Updating Standards for Compliance

Sponsors of registered apprenticeship programs will also need to develop language or make adjustments and updates to existing standards to comply with the proposed changes to part 30. The Department estimates that updating standards to comply with part 30 will mainly be removing items currently required by part 30 and therefore estimates the burden will be minimal. The Department assumes news sponsors will take a similar amount of time to ensure the standards they develop do not conflict with part 30. Accordingly, the Department estimates the average response time for sponsors to ensure standards comply with part 30 is 20 minutes (0.33 hours). Thus, the resulting cost per small entity is \$11.85 (0.33 × \$35.91).

For a hypothetical small entity in the top five industry categories, the first-year cost of this rule is \$118.89 (\$107.04 + \$11.85). There are no costs in subsequent years.

Total Cost Burden for Small Entities

For a hypothetical small entity in the top five industry categories, the first-year cost of this rule is \$118.89 (\$107.04 + \$11.85). There are no costs in subsequent years.

The total cost impacts, as a percentage of revenue, are all well below the 3 percent threshold for determining a significant economic impact.

The Department used the following steps to estimate the cost of the proposed rule per registered apprenticeship program sponsor as a percentage of annual receipts. First, the Department used the Small Business Administration's Table of Small

Business Size Standards to determine the size thresholds for small entities within each major industry.⁴⁶ Next the Department obtained data on the number of firms, number of employees, and annual revenue by industry and firm size category from the Census Bureau's Statistics of U.S. Businesses.⁴⁷ Then, the Department divided the estimated first-year cost per sponsor by the average annual receipts per firm to determine whether the proposed rule would have a significant economic impact on sponsors in each size category.⁴⁸ Finally, the Department divided the number of firms in each size category by the total number of small firms in the industry to determine whether the proposed rule would have a significant economic impact on a substantial number of small entities.⁴⁹

The results are presented in the following five tables, one for each major industry sector with the most registered apprenticeship programs and for which data are available: Construction, Educational Services, Manufacturing, Other Services, and Healthcare. As shown in the five tables below, the first-year costs for sponsors in these five industries are not expected to have a significant economic impact (3 percent or more) on small entities of any size. Therefore, the Department certifies that the proposed rule is not expected to have a significant economic impact on a substantial number of small entities.

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⁴⁶ U.S. Small Business Administration, "Table of Small Business Size Standards," Mar. 17, 2023, <https://www.sba.gov/document/support-table-size-standards>. The size standards, which are expressed in either average annual receipts or number of employees, indicate the maximum allowed for a business in each subsector to be considered small.

⁴⁷ U.S. Census Bureau, "Statistics of U.S. Businesses," <https://www.census.gov/programs-surveys/susb/data.html>.

⁴⁸ For purposes of this analysis, the Department used a 3-percent threshold for "significant economic impact." The Department has used a 3-percent threshold in prior rulemakings.

⁴⁹ For purposes of this analysis, the Department used a 15-percent threshold for "substantial number of small entities." The Department has used a 15-percent threshold in prior rulemakings.

⁴³ **Federal Register:** Apprenticeship Programs; Equal Employment Opportunity.

⁴⁴ See Small Business Association, *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act*, 17–19 (June 2010), available at <http://www.sba.gov/content/guide-government-agencies-how-comply-with-regulatory-flexibility-act-0> (last accessed Apr. 7, 2011). The Department has used the 3 percent threshold in previous regulations.

⁴⁵ A large entity could have a single apprentice or a small entity could have multiple apprentices.

Construction Industry							
Small Business Size Standard: \$19.0 million – \$45.0 million							
	Number of Firms ¹	Number of Firms as Percent of Small Firms in Industry ²	Total Number of Employees ³	Annual Receipts ⁴	Average Receipts per Firm ⁵	First Year Cost per Firm	First Year Cost per Firm as Percent of Receipts ⁶
Enterprises with receipts below \$100,000	167,522	24.0%	156,090	\$8,725,609,000	\$52,086	\$119	0.2%
Enterprises with receipts of \$100,000 to \$499,999	247,074	35.5%	544,141	\$59,292,938,000	\$239,980	\$119	0.0%
Enterprises with receipts of \$500,000 to \$999,999	89,351	12.8%	444,318	\$64,312,630,000	\$719,775	\$119	0.0%
Enterprises with receipts of \$1,000,000 to \$2,499,999	95,739	13.7%	828,261	\$151,543,429,000	\$1,582,881	\$119	0.0%
Enterprises with receipts of \$2,500,000 to \$4,999,999	45,814	6.6%	707,745	\$160,596,928,000	\$3,505,412	\$119	0.0%
Enterprises with receipts of \$5,000,000 to \$7,499,999	17,860	2.6%	416,512	\$108,352,122,000	\$6,066,748	\$119	0.0%
Enterprises with receipts of \$7,500,000 to \$9,999,999	9,233	1.3%	283,971	\$79,262,068,000	\$8,584,649	\$119	0.0%
Enterprises with receipts of \$10,000,000 to \$14,999,999	9,925	1.4%	401,418	\$119,793,304,000	\$12,069,854	\$119	0.0%
Enterprises with receipts of \$15,000,000 to \$19,999,999	5,029	0.7%	270,176	\$85,738,468,000	\$17,048,810	\$119	0.0%
Enterprises with receipts of \$20,000,000 to \$24,999,999	3,089	0.4%	200,568	\$67,308,726,000	\$21,789,811	\$119	0.0%
Enterprises with receipts of \$25,000,000 to \$29,999,999	2,011	0.3%	150,472	\$53,427,366,000	\$26,567,561	\$119	0.0%
Enterprises with receipts of \$30,000,000 to \$34,999,999	1,396	0.2%	119,403	\$43,667,793,000	\$31,280,654	\$119	0.0%
Enterprises with receipts of \$35,000,000 to \$39,999,999	1,056	0.2%	99,968	\$37,941,329,000	\$35,929,289	\$119	0.0%
Enterprises with receipts of \$40,000,000 to \$49,999,999	1,466	0.2%	166,727	\$63,454,897,000	\$43,284,377	\$119	0.0%
¹ Source: U.S. Census Bureau, Statistics of U.S. Businesses.							
² Number of firms ÷ Small firms in industry							
³ Source: U.S. Census Bureau, Statistics of U.S. Businesses.							
⁴ Source: U.S. Census Bureau, Statistics of U.S. Businesses.							
⁵ Annual receipts ÷ Number of firms							
⁶ First year cost per firm with 7% discounting ÷ Average receipts per firm							
⁷ Annualized cost per firm with 7% discounting ÷ Average receipts per firm							

Educational Services Industry							
Small Business Size Standard: \$9.0 million – \$47.0 million							
	Number of Firms	Number of Firms as Percent of Small Firms in Industry	Total Number of Employees	Annual Receipts	Average Receipts per Firm	First Year Cost per Firm	First Year Cost per Firm as Percent of Receipts
Enterprises with receipts below \$100,000	22,439	24.3%	42,944	\$1,072,923,000	\$47,815	\$119	0.2%
Enterprises with receipts of \$100,000 to \$499,999	37,156	40.3%	197,950	\$9,253,888,000	\$249,055	\$119	0.0%
Enterprises with receipts of \$500,000 to \$999,999	11,425	12.4%	139,745	\$8,015,282,000	\$701,556	\$119	0.0%
Enterprises with receipts of \$1,000,000 to \$2,499,999	9,837	10.7%	237,256	\$15,395,145,000	\$1,565,024	\$119	0.0%
Enterprises with receipts of \$2,500,000 to \$4,999,999	4,948	5.4%	227,231	\$17,182,220,000	\$3,472,559	\$119	0.0%
Enterprises with receipts of \$5,000,000 to \$7,499,999	2,051	2.2%	142,147	\$12,111,348,000	\$5,905,094	\$119	0.0%
Enterprises with receipts of \$7,500,000 to \$9,999,999	1,085	1.2%	99,135	\$8,953,268,000	\$8,251,860	\$119	0.0%
Enterprises with receipts of \$10,000,000 to \$14,999,999	1,217	1.3%	149,025	\$13,862,557,000	\$11,390,762	\$119	0.0%
Enterprises with receipts of \$15,000,000 to \$19,999,999	788	0.9%	130,304	\$12,669,721,000	\$16,078,326	\$119	0.0%
Enterprises with receipts of \$20,000,000 to \$24,999,999	405	0.4%	83,052	\$8,138,742,000	\$20,095,659	\$119	0.0%
Enterprises with receipts of \$25,000,000 to \$29,999,999	266	0.3%	72,713	\$6,484,352,000	\$24,377,263	\$119	0.0%
Enterprises with receipts of \$30,000,000 to \$34,999,999	193	0.2%	53,118	\$5,395,885,000	\$27,957,953	\$119	0.0%
Enterprises with receipts of \$35,000,000 to \$39,999,999	157	0.2%	49,519	\$4,946,014,000	\$31,503,274	\$119	0.0%
Enterprises with receipts of \$40,000,000 to \$49,999,999	230	0.2%	84,073	\$8,636,464,000	\$37,549,843	\$119	0.0%

Manufacturing Industry							
Small Business Size Standard: 500 – 1,500 employees							
	Number of Firms	Number of Firms as Percent of Small Firms in Industry	Total Number of Employees	Annual Receipts	Average Receipts per Firm	First Year Cost per Firm	First Year Cost per Firm as Percent of Receipts
Enterprises with 0-4 employees	102,242	41.5%	188,002	\$41,641,473,000	\$407,283	\$119	0.0%
Enterprises with 5-9 employees	45,821	18.6%	306,025	\$54,272,680,000	\$1,184,450	\$119	0.0%
Enterprises with 10-19 employees	37,549	15.2%	511,380	\$97,477,689,000	\$2,596,013	\$119	0.0%
Enterprises with 20-99 employees	46,089	18.7%	1,872,005	\$434,974,512,000	\$9,437,708	\$119	0.0%
Enterprises with 100-499 employees	12,397	5.0%	2,162,360	\$684,189,119,000	\$55,189,894	\$119	0.0%
Enterprises with 500-749 employees	1,127	0.5%	526,397	\$212,921,994,000	\$188,928,122	\$119	0.0%
Enterprises with 750-999 employees	608	0.2%	370,263	\$145,396,128,000	\$239,138,368	\$119	0.0%
Enterprises with 1,000-1,499 employees	578	0.2%	487,897	\$230,429,698,000	\$398,667,298	\$119	0.0%

Other Services Industry							
Small Business Size Standard: \$8.0 million – \$47.0 million							
	Number of Firms	Number of Firms as Percent of Small Firms in Industry	Total Number of Employees	Annual Receipts	Average Receipts per Firm	First Year Cost per Firm	First Year Cost per Firm as Percent of Receipts
Enterprises with receipts below \$100,000	170,736	24.6%	255,297	\$8,652,069,000	\$50,675	\$119	0.2%
Enterprises with receipts of \$100,000 to \$499,999	317,048	45.7%	1,077,568	\$78,960,123,000	\$249,048	\$119	0.0%
Enterprises with receipts of \$500,000 to \$999,999	102,517	14.8%	754,571	\$71,799,849,000	\$700,370	\$119	0.0%
Enterprises with receipts of \$1,000,000 to \$2,499,999	68,210	9.8%	955,461	\$103,187,937,000	\$1,512,798	\$119	0.0%
Enterprises with receipts of \$2,500,000 to \$4,999,999	20,419	2.9%	564,101	\$69,277,561,000	\$3,392,799	\$119	0.0%
Enterprises with receipts of \$5,000,000 to \$7,499,999	6,414	0.9%	280,574	\$37,605,902,000	\$5,863,097	\$119	0.0%
Enterprises with receipts of \$7,500,000 to \$9,999,999	2,783	0.4%	161,164	\$22,887,699,000	\$8,224,110	\$119	0.0%
Enterprises with receipts of \$10,000,000 to \$14,999,999	2,571	0.4%	195,893	\$28,880,096,000	\$11,233,021	\$119	0.0%
Enterprises with receipts of \$15,000,000 to \$19,999,999	1,264	0.2%	119,626	\$19,348,930,000	\$15,307,698	\$119	0.0%
Enterprises with receipts of \$20,000,000 to \$24,999,999	692	0.1%	72,568	\$13,156,352,000	\$19,012,069	\$119	0.0%
Enterprises with receipts of \$25,000,000 to \$29,999,999	506	0.1%	63,532	\$11,408,938,000	\$22,547,308	\$119	0.0%
Enterprises with receipts of \$30,000,000 to \$34,999,999	325	0.0%	42,921	\$8,458,331,000	\$26,025,634	\$119	0.0%
Enterprises with receipts of \$35,000,000 to \$39,999,999	292	0.0%	37,383	\$8,496,715,000	\$29,098,339	\$119	0.0%
Enterprises with receipts of \$40,000,000 to \$49,999,999	326	0.0%	49,042	\$10,596,957,000	\$32,506,003	\$119	0.0%

Health Care and Social Assistance Industry							
Small Business Size Standard: \$9.0 million – \$47.0 million							
	Number of Firms	Number of Firms as Percent of Small Firms in Industry	Total Number of Employees	Annual Receipts	Average Receipts per Firm	First Year Cost per Firm	First Year Cost per Firm as Percent of Receipts
Enterprises with receipts below \$100,000	105,782	16.3%	144,258	\$5,157,367,000	\$48,755	\$119	0.2%
Enterprises with receipts of \$100,000 to \$499,999	247,273	38.0%	919,768	\$66,746,907,000	\$269,932	\$119	0.0%
Enterprises with receipts of \$500,000 to \$999,999	130,435	20.0%	1,066,795	\$92,688,993,000	\$710,614	\$119	0.0%
Enterprises with receipts of \$1,000,000 to \$2,499,999	102,005	15.7%	1,733,292	\$155,576,671,000	\$1,525,187	\$119	0.0%
Enterprises with receipts of \$2,500,000 to \$4,999,999	32,793	5.0%	1,269,403	\$112,848,383,000	\$3,441,234	\$119	0.0%
Enterprises with receipts of \$5,000,000 to \$7,499,999	11,292	1.7%	768,478	\$67,880,384,000	\$6,011,369	\$119	0.0%
Enterprises with receipts of \$7,500,000 to \$9,999,999	6,073	0.9%	587,923	\$51,322,879,000	\$8,450,993	\$119	0.0%
Enterprises with receipts of \$10,000,000 to \$14,999,999	6,282	1.0%	843,098	\$74,388,140,000	\$11,841,474	\$119	0.0%
Enterprises with receipts of \$15,000,000 to \$19,999,999	3,193	0.5%	582,465	\$52,937,196,000	\$16,579,141	\$119	0.0%
Enterprises with receipts of \$20,000,000 to \$24,999,999	1,945	0.3%	432,978	\$41,376,894,000	\$21,273,467	\$119	0.0%
Enterprises with receipts of \$25,000,000 to \$29,999,999	1,297	0.2%	333,840	\$33,402,569,000	\$25,753,715	\$119	0.0%
Enterprises with receipts of \$30,000,000 to \$34,999,999	939	0.1%	287,523	\$28,762,117,000	\$30,630,583	\$119	0.0%
Enterprises with receipts of \$35,000,000 to \$39,999,999	672	0.1%	251,011	\$23,637,148,000	\$35,174,327	\$119	0.0%
Enterprises with receipts of \$40,000,000 to \$49,999,999	903	0.1%	357,594	\$37,602,128,000	\$41,641,338	\$119	0.0%

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5. Relevant Federal Rules Duplicating, Overlapping, or Conflicting With the Proposed

The Department has not identified any federal rules that may duplicate, overlap, or conflict with this proposed rule. Instead, this proposed rule is removing duplication that currently exists because sponsors will no longer have to refer complaints to the SAAs. Requiring sponsors to refer complaints to the SAAs is duplicative because, in practice, SAAs referred complaints to the appropriate non-discrimination enforcement agencies and employers are already required to refer such complaints to the relevant non-discrimination enforcement agency.

6. Alternatives to the Proposed Rule

Regarding significant alternatives to the proposed rule that accomplishes the objectives of applicable statutes and minimizes any significant economic impact of the proposed rule on small entities, the Department believes there are limited options. Repealing part 30 entirely would still require sponsors who are small entities to update their standards to remove reference to part 30, costing \$11.85 per sponsor. There could be lower to no rule familiarization costs for small entities if part 30 was repealed entirely, since there would be no rule that entities would have to be familiarized with, however sponsors would still need to be informed of the change and may review the **Federal Register** notice. However, the Department believes that removing part 30 entirely would prevent conformity

across the Registered Apprenticeship System, as some states may choose to impose additional requirements for sponsors to conduct legally questionable affirmative action or other EEO activities that expand beyond the scope of the Department's proposed part 30 rule. If part 30 was repealed entirely and states were to impose additional EEO requirements, these new requirements and the resulting confusion from a patchwork of different requirements across jurisdictions could ultimately lead to greater costs for small entities.⁵⁰

Alternatively, the Department considered publishing a direct final rule or an interim final rule to make changes to the part 30 regulation. However, the

⁵⁰ The Department is not able to estimate or monetize the cost of the additional potential EEO requirements states may pursue if part 30 is repealed, because it is unknown what requirements states would impose on small entities.

Department determined that these approaches to rulemaking would have given smaller entities no advanced notice of changes to the part 30 regulation, given that the changes would take effect immediately upon (or soon after) publication, and would have denied small entities the opportunity to provide robust feedback on the changes. Accordingly, the Department believes a proposed rule is more appropriate and will allow the Department to better account for small businesses' viewpoint and needs.

C. Paperwork Reduction Act

The purpose of the PRA, 44 U.S.C. 3501 *et seq.*, includes minimizing the paperwork burden on affected entities. The PRA requires certain actions before an agency can adopt or revise a collection of information, including publishing for public comment a summary of the collection of information and a brief description of the need for and proposed use of the information.

As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program to provide the public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the PRA. See 44 U.S.C. 3506(C)(2)(A). Furthermore, the PRA requires all Federal agencies to analyze proposed and final regulations for potential time burdens on the regulated community created by provisions in the regulations that require any party to obtain, maintain, retain, report, or disclose information. The ICRs also must be submitted to OMB for approval. Such submissions often accompany a proposed and final rulemaking that seeks to modify an existing IC, introduce new ICs, or both.

A Federal agency may not conduct or sponsor a collection of information unless it is approved by OMB under the PRA and displays a currently valid OMB control number. The public also is not required to respond to a collection of information unless it displays a currently valid OMB control number. In addition, notwithstanding any other provisions of law, no person will be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number. See 44 U.S.C. 3512.

This rulemaking affects specific information collections (OMB Control Number 1205–0223, which includes OMB-approved forms ETA–671, ETA–9186, and ETA–9039). Changes to these

collections will be communicated through an upcoming 60-day **Federal Register Notice**.

1. Labor Standards and Equal Employment Opportunity for Registered Apprenticeship Programs—Registration and Reporting Requirements

Agency: DOL–ETA.

Title of Collection: Labor Standards and Equal Employment Opportunity for Registered Apprenticeship Programs—Registration and Reporting Requirements.

Type of Review: Revision.

OMB Control Number: 1205–0223.

Description:

Affected Public: State, Local, and Tribal Governments; Private Sector; Individuals or Households.

Obligation to Respond: Required to Obtain or Retain Benefits.

Estimated Total Annual Respondents: placeholder.

Estimated Total Annual Responses: placeholder.

Estimated Total Annual Burden Hours: placeholder.

Estimated Total Annual Burden Costs: placeholder.

Estimated Total Annual Other Burden Costs: placeholder.

Regulations Sections: placeholder.

D. Congressional Notification

As required by 5 U.S.C. 801, if finalized, DOL will report to Congress on the promulgation of this rule before its effective date. The report will state that it has been determined that the rule is a “major rule” as defined by 5 U.S.C. 804.

E. Executive Order 13132 (Federalism)

The Department has reviewed this proposed rule in accordance with E.O. 13132 and found that it will have Federalism implications because it will have substantial direct effects on States. Although matters of Federalism in the National Registered Apprenticeship System are primarily established through part 29, Labor Standards for Registration of Apprenticeship Programs, which establishes the requirements for the recognition of SAAs as Registration Agencies, the proposed revisions to part 30 also have direct effect on a State's method of administering registered apprenticeship for Federal purposes. In particular, the proposed rule requires an SAA that seeks to obtain or maintain recognition as the Registration Agency for Federal purposes, submit State apprenticeship legislation, regulations, policies, and operational procedures related to the nondiscrimination obligation conformity requirements of part 30, and

requires all program sponsors registered with the State for Federal purposes to comply with the State plan. This NPRM also requires OA's Administrator to provide written concurrence on any subsequent modifications to the State plan, as provided in proposed § 29.13(b)(9).

The Department has determined that these requirements are essential to ensure that SAAs conform to the new requirements of part 30, as a precondition for recognition. OA regularly consults and collaborates with State partners and organizations, including when developing and promulgating updates to parts 29 or 30 impacting the National Apprenticeship System. The Department and OA will continue consulting and collaborating with State partners, which the Department views as central to OA's role in promoting and maintaining quality registered apprenticeship programs.

F. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1532, requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a final rule that may result in \$100 million or more in expenditures (adjusted annually for inflation) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector. The current threshold after adjustment for inflation is \$177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product.

This proposed rule does not meet or exceed the expenditure threshold in any one year when adjusted for inflation. The requirements of title II of UMRA, therefore, do not apply, and the Department has not prepared a statement under the Act.

G. Executive Order 13175 (Indian Tribal Governments)

The Department has reviewed this proposed rule in accordance with E.O. 13175 and has determined that it does not have Tribal implications. The proposed rule does not have substantial direct effects 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.

List of Subjects

29 CFR Part 29

Apprenticeship agreements and complaints, Apprenticeship programs,

Program standards, Registration and deregistration, Sponsor eligibility, State Apprenticeship Agency recognition and derecognition, Suitability for registered apprenticeship criteria.

29 CFR Part 30

Administrative practice and procedure, Apprenticeship, Employment, Equal employment opportunity, Reporting and recordkeeping requirements, Training.

For the reasons stated in the preamble, the Employment and Training Administration proposes to amend 29 CFR parts 29 and 30 as follows:

PART 29—LABOR STANDARDS FOR THE REGISTRATION OF APPRENTICESHIP PROGRAMS

■ 1. The authority citation for part 29 continues to read as follows:

Authority: 29 U.S.C. 50; 40 U.S.C. 3145; 5 U.S.C. 301; 5 U.S.C. App. P. 534.

■ 2. Amend § 29.3 by revising paragraph (b)(2) to read as follows:

§ 29.3 Eligibility and procedure for registration of an apprenticeship program.

* * * * *

(b) * * *

(2) It is in conformity with the requirements of the Department's nondiscrimination in apprenticeship regulation at 29 CFR part 30, as amended.

* * * * *

■ 3. Amend § 29.5 by revising paragraph (b)(21) to read as follows:

§ 29.5 Standards of apprenticeship.

* * * * *

(b) * * *

(21) Compliance with 29 CFR part 30, including a statement that the program will be conducted, operated, and administered in conformity with applicable provisions of 29 CFR part 30, as amended, or if applicable, an approved State plan for nondiscrimination in apprenticeship.

* * * * *

■ 4. Amend § 29.6 by revising paragraph (b)(1)(ii) to read as follows:

§ 29.6 Program performance standards.

* * * * *

(b) * * *

(1) * * *

(ii) Compliance Reviews; and

* * * * *

■ 5. Amend § 29.7 by revising paragraph (j) and revising paragraph (l) to read as follows:

§ 29.7 Apprenticeship agreement.

* * * * *

(j) A statement that the apprentice will not be illegally discriminated against on the basis of race, color, religion, national origin, sex, age (40 or older), genetic information, or disability in any phase of apprenticeship employment and training.

* * * * *

(l) A request for demographic data about the apprentice.

■ 6. Amend § 29.11 by revising paragraph (b) to read as follows:

§ 29.11 Limitations.

* * * * *

(b) Any special provision for veterans in the standards, apprentice qualifications or operation of the program, or in the apprenticeship agreement, which is not prohibited by law, Executive Order, or authorized regulation.

■ 7. Amend § 29.12 by revising paragraph (a) to read as follows:

§ 29.12 Complaints.

(a) This section is not applicable to any complaint concerning illegal discrimination; all such complaints received by a Registration Agency must be submitted to the relevant enforcement authority, as set forth in 29 CFR 30.4, or according to applicable provisions of the State Plan for nondiscrimination.

* * * * *

■ 8. Amend § 29.13 by revising paragraphs (a)(3), (b)(4), (h)(2), and (j)(1) and (2) to read as follows:

§ 29.13 Recognition of State Apprenticeship Agencies.

(a) * * *

(3) The State Apprenticeship Agency must submit a State Plan for nondiscrimination in apprenticeship that conforms to the requirements published in 29 CFR part 30;

* * * * *

(b) * * *

(4) Establish policies and procedures to prohibit illegal discrimination in registered apprenticeship programs in conformity with the requirements set forth in 29 CFR part 30;

* * * * *

(h) * * *

(2) Provide all apprenticeship program standards, apprenticeship agreements, completion records, cancellation and suspension records, Compliance Review files, and any other documents relating to the State's apprenticeship programs, to the Department; and

* * * * *

(j) * * *

(1) An apprenticeship program submitted to a State Registration Agency

for registration must, for Federal purposes, be in conformity with the State apprenticeship law, regulations, and with the State Plan for nondiscrimination in apprenticeship as submitted to, and approved by, the Office of Apprenticeship pursuant to 29 CFR part 30.

(2) In the event that a State Apprenticeship Agency is not recognized by the Office of Apprenticeship for Federal purposes or that such recognition has been withdrawn, or if no State Apprenticeship Agency exists, registration with the Office of Apprenticeship may be requested. Such registration must be granted if the program is conducted, administered, and operated in accordance with the requirements of this part and the nondiscrimination in apprenticeship regulation in 29 CFR part 30, as amended.

■ 9. Amend § 29.14 by revising paragraphs (a) and (h)(1) to read as follows:

§ 29.14 Derecognition of State Apprenticeship Agencies.

* * * * *

(a) Derecognition proceedings for failure to adopt or properly enforce a State Plan for nondiscrimination in apprenticeship must be processed in accordance with the procedures prescribed in this part.

* * * * *

(h) * * *

(1) Provide all apprenticeship program standards, apprenticeship agreements, completion records, cancellation and suspension records, Compliance Review files, and any other documents relating to the State's apprenticeship programs, to the Department.

* * * * *

■ 11. Revise part 30 to read as follows:

PART 30—PROHIBITING ILLEGAL DISCRIMINATION IN REGISTERED APPRENTICESHIP PROGRAMS

Sec.

30.1 Purpose and applicability.

30.2 Definitions.

30.3 Nondiscrimination standards applicable to all sponsors.

30.4 Complaints.

30.5 Nondiscrimination compliance reviews and enforcement.

30.6 Reinstatement of program registration.

30.7 State apprenticeship agencies.

30.8 Exemptions.

Authority: Sec. 1, 50 Stat. 664, as amended (29 U.S.C. 50; 40 U.S.C. 276c; 5 U.S.C. 301); Reorganization Plan No. 14 of 1950, 64 Stat. 1267, 3 CFR 1949–53 Comp. p. 1007.

§ 30.1 Purpose and applicability.

(a) *Purpose.* The purpose of this part is to establish a uniform Federal standard prohibiting illegal discrimination against apprentices (including applicants for apprenticeship) in registered apprenticeship programs. To achieve this purpose, this part sets forth nondiscrimination requirements for program sponsors and State Apprenticeship Agencies (SAAs), and clarifies the scope and content of compliance reviews, compliance assistance, and enforcement actions by Registration Agencies.

(b) *Applicability.* This part applies to all sponsors of apprenticeship programs registered with either the U.S. Department of Labor or a recognized SAA.

§ 30.2 Definitions.

The definitions in § 29.2 of this title also apply to this part.

§ 30.3 Nondiscrimination standards applicable to all sponsors.

Compliance with Federal and State nondiscrimination laws. Registered apprenticeship program sponsors must comply with all applicable Federal and State laws and regulations prohibiting illegal discrimination on the basis of race, color, religion, national origin, sex, age (40 or older), genetic information, or disability. Failure to comply with such nondiscrimination laws is grounds for deregistration or the imposition of other enforcement actions in accordance with § 30.5(c), if such non-compliance is related to illegal discrimination against apprentices or an applicant to an apprenticeship program with respect to any benefit, term, or condition of employment associated with an apprenticeship.

§ 30.4 Complaints.

Referral of complaints to other agencies. If the Registration Agency receives any complaints from apprentices (including applicants for apprenticeship) alleging illegal discrimination, it will immediately refer the individual to:

- (a) The EEOC;
- (b) The United States Attorney General; or
- (c) For an SAA, to its Fair Employment Practices Agency.

§ 30.5 Nondiscrimination compliance reviews and enforcement.

(a) *Conduct of compliance reviews.* Concurrently with a Registration Agency's review of a registered apprenticeship program for conformity with the requirements of 29 CFR part 29, a Registration Agency will assess a

program's compliance with the nondiscrimination requirement of section 30.3(a) of this part.

(b) *Determining compliance.* For the purpose of determining compliance under this part, the Registration Agency may initiate enforcement actions against a sponsor for failure to comply with the nondiscrimination requirement at § 30.3(a) in instances where a final determination of a violation of an applicable nondiscrimination law, without any remaining right to appeal, has been made by an enforcement entity or court with jurisdiction over a matter, and authority to issue a final determination, relating to an apprentice or an applicant to an apprenticeship program.

(c) *Compliance and enforcement actions.* Upon learning of a final determination made by an enforcement entity or court with respect to a sponsor's violation of an applicable nondiscrimination law (as described in paragraph (b) of this section), the Registration Agency may work with the sponsor to develop a compliance action plan that aligns with the remedy prescribed by the enforcement entity or court and brings the program into compliance with this part. If the Registration Agency determines that a compliance action plan is not being implemented in accordance with the remedy prescribed by the enforcement entity or court, the Registration Agency may initiate enforcement actions that will remain in place until the violation is resolved to the satisfaction of the Registration Agency. Enforcement actions by the Registration Agency include:

- (1) Suspension of the sponsor's right to register new apprentices, or
- (2) The initiation of deregistration proceedings set forth in part 29 of this subtitle.

§ 30.6 Reinstatement of program registration.

An apprenticeship program that has been deregistered pursuant to this part may be reinstated by the Registration Agency upon presentation of adequate evidence that the apprenticeship program is operating in accordance with this part.

§ 30.7 State apprenticeship agencies.

(a) *State laws pertaining to apprenticeship.* Within 1 year of the effective date of this final rule, unless an extension for good cause is sought and granted by the Administrator, an SAA that seeks to obtain or maintain recognition under § 29.13 of this title must submit a State plan for nondiscrimination in apprenticeship, as

described in paragraph (b) of this section, that demonstrates that the State's apprenticeship laws, regulations, policies, and operational procedures related to the nondiscrimination obligation conform only to the requirements of this part.

(b) *Elements of the State plan for nondiscrimination in apprenticeship.*

(1) The State plan for nondiscrimination in apprenticeship must—

(i) Include current State statutes, regulations, policies and operational procedures pertaining exclusively to nondiscrimination in apprenticeship that conform only to the requirements of this part; and

(ii) Require all apprenticeship programs registered with the State for Federal purposes to comply with the requirements of the State's plan within 180 days from the date that OA provides written approval of the State plan submitted under paragraph (a).

(2) Upon receipt of the State plan, OA will review the plan to determine if the plan conforms to this part. OA will:

(i) Grant the SAA continued recognition during this review period;

(ii) Provide technical assistance, if necessary, to facilitate conformity, and provide written notification of the areas of nonconformity, if any; and

(iii) Upon successful completion of the review process, notify the SAA of OA's determination that the State plan conforms to this part.

(3) If the State does not submit a revised State plan that adequately responds to OA's technical assistance within 90 days from the date that OA provides the SAA with written notification of the areas of nonconformity, OA is authorized to initiate the process set forth in § 29.14 of this title to rescind recognition of the SAA.

(4) An SAA that seeks to obtain or maintain recognition must obtain the Administrator's written concurrence in any proposed State plan, as well as any subsequent modification to that plan, as provided in § 29.13(b)(9) of this title.

(c) *Recordkeeping requirements.* A recognized SAA must keep all records pertaining to program compliance reviews and any other records pertinent to a determination of compliance with this part. These records must be maintained for five years from the date of their creation.

(d) *Retention of authority.* As provided in § 29.13 of this subtitle, OA retains the full authority to:

(1) Conduct compliance reviews of all registered apprenticeship programs;

(2) Deregister for Federal purposes an apprenticeship program registered with

a recognized SAA as provided in §§ 29.8(b) and 29.10 of this chapter; and

(e) *Derecognition*. A recognized SAA that fails to comply with the requirements of this section will be subject to derecognition proceedings, as provided in § 29.14 of this chapter.

§ 30.8 Exemptions.

Requests for exemption from these regulations, or any part thereof, must be made in writing to the Registration Agency and must contain a statement of reasons supporting the request. Exemptions may be granted for good cause by the Registration Agency. SAAs must receive approval to grant an exemption from the Administrator, prior to granting an exemption from these regulations.

Susan Frazier,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2025–12317 Filed 6–30–25; 8:45 am]

BILLING CODE 4510–FR–P

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 552

RIN 1235–AA51

Application of the Fair Labor Standards Act to Domestic Service

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Proposed rule; request for comments.

SUMMARY: In 1974, Congress applied the Fair Labor Standards Act (FLSA) to “domestic service” employees, but exempted employees who provide “companionship services” from the minimum wage and overtime requirements and also exempted live-in domestic service employees from overtime. In 1975, the Department promulgated regulations defining companionship services and permitting third party employers to claim these exemptions. These regulations remained substantially unchanged for nearly 40 years. In 2013, the Department revised the regulations to narrow the definition of companionship services and prevent third party employers from claiming either of the exemptions. Because the Department is concerned that the 2013 regulations might not reflect the best interpretation of the FLSA and might discourage essential companionship services by making these services more expensive, the Department is proposing to return to the 1975 regulations. This summary can be found at [https://](https://www.regulations.gov)

www.regulations.gov by searching by the RIN: 1235–AA51.

DATES: Comments must be received by September 2, 2025.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 1235–AA51, by either of the following methods:

- *Electronic Comments:* Submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Address written submissions to: Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210.

Instructions: Response to this NPRM is voluntary. The Department requests that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this NPRM. Commenters submitting file attachments on <https://www.regulations.gov> are advised that uploading text-recognized documents—*i.e.*, documents in a native file format or documents which have undergone optical character recognition (OCR)—enable staff at the Department to more easily search and retrieve specific content included in your comment for consideration.

Anyone who submits a comment (including duplicate comments) should understand and expect that the comment, including any personal information provided, will become a matter of public record and will be posted without change to <https://www.regulations.gov>. The Department posts comments gathered and submitted by a third-party organization as a group under a single document ID number on <https://www.regulations.gov>. All comments must be received by 11:59 p.m. ET on September 2, 2025, for consideration in this rulemaking; comments received after the comment period closes will not be considered.

The Department strongly recommends that commenters submit their comments electronically via <https://www.regulations.gov> to ensure timely receipt prior to the close of the comment period. Please submit only one copy of your comments by only one method.

Docket: Go to the Federal eRulemaking Portal at <https://www.regulations.gov> for access to the rulemaking docket, including any background documents and the plain-language summary of the proposed rule of not more than 100 words in length required by the Providing Accountability Through Transparency Act of 2023.

FOR FURTHER INFORMATION CONTACT:

Daniel Navarrete, Director, Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–0406 (this is not a toll-free number). Alternative formats are available upon request by calling 1–866–487–9243. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

Questions of interpretation or enforcement of the agency’s existing regulations may be directed to the nearest WHD district office. Locate the nearest office by calling the WHD’s toll-free help line at (866) 4US–WAGE ((866) 487–9243) between 8 a.m. and 5 p.m. in your local time zone, or log onto WHD’s website at <https://www.dol.gov/agencies/whd/contact/local-offices> for a nationwide listing of WHD district and area offices.

SUPPLEMENTARY INFORMATION:

I. Background

The FLSA requires that most employees in the United States must be paid at least the federal minimum wage (currently \$7.25 per hour) for all hours worked and overtime pay at not less than time and one-half the employee’s regular rate of pay for all hours worked over 40 hours in a workweek.¹ The FLSA also requires covered employers to “make, keep, and preserve” certain records regarding employees,² though recordkeeping requirements are relaxed for employees who are exempt from the Act’s wage and hour provisions.³

Prior to 1974, the FLSA’s minimum wage and overtime compensation provisions did not apply to domestic service workers unless those workers were employed by covered enterprises (generally those that had at least a certain annual dollar threshold in business). In 1974, Congress amended the FLSA to extend coverage to all domestic service workers, including those employed by private households or small companies previously not covered by the Act.⁴ At the same time, Congress created FLSA exemptions for two categories of domestic service employees. First, in section 13(a)(15), Congress added an exemption from the Act’s minimum wage and overtime compensation requirements for “any employee employed on a casual basis in

¹ See 29 U.S.C. 206(a), 207(a).

² See 29 U.S.C. 211(c).

³ See 29 CFR part 516 Subpart B.

⁴ See Fair Labor Standards Amendments of 1974, Public Law 93–259 § 7, 88 Stat. 55, 62 (1974).

domestic service employment to provide babysitting services or any employee employed in domestic service employment to provide companionship services for individuals who (because of age or infirmity) are unable to care for themselves (as such terms are defined and delimited by regulations of the Secretary).”⁵ Second, in section 13(b)(21), Congress added an exemption from the overtime requirement (but not the minimum wage requirement) for “any employee who is employed in domestic service in a household and who resides in such household.”⁶ Finally, Congress authorized the Department “to prescribe necessary rules, regulations, and orders with regard to the [1974 FLSA Amendments],”⁷ and specifically instructed the Department to “define and delimit” the terms “domestic service employment” and “companionship services.”⁸

In 1975, the Department promulgated regulations applying the FLSA to domestic service employment at 29 CFR part 552, including provisions addressing the companionship and live-in domestic service employee exemptions.⁹ These regulations defined companionship services as “fellowship, care, and protection for a person who . . . cannot care for his or her own needs,” which included “household work related to the person’s care such as meal preparation, bed making, washing of clothes, and other similar services” and could include other general household work not exceeding “20 percent of the total weekly hours worked.”¹⁰ Additionally, the 1975 regulations permitted third party employers, or employers of home care workers other than the individuals receiving care or their families or households, to claim both the companionship services and live-in domestic service employee exemptions.¹¹

These regulations remained substantially unchanged for almost 40 years. In 2007, the Supreme Court issued a unanimous decision affirming the validity of the third-party employer provision at 29 CFR 522.109 (1975), holding in relevant part that neither the statute nor the legislative history provides a definitive answer as to whether third-party employers may avail themselves of these exemptions

and that the third-party employer regulation fell within the Department’s broad scope of delegated rulemaking authority.¹²

In 2013, the Department published a final rule that revised its companionship services and live-in employee regulations.¹³ Among other changes, the 2013 rule significantly narrowed the scope of the exemptions in two ways.

First, the 2013 rule altered the definition of exempt “companionship services” to include the provision of “fellowship” (such as social, physical, and mental activities), “protection” (meaning to be present with the person to monitor their well-being), and “care” (meaning assisting with activities of daily living, such as dressing, grooming, feeding, bathing, toileting, and transferring, and instrumental activities of daily living, such as meal preparation, light housework, managing finances, assistance with daily taking of medications, and arranging medical care), but only if such “care” does not exceed 20 percent of the total hours worked per person and per workweek.¹⁴ These changes significantly reduced the scope of permissible job duties for exempt companion workers; whereas under the 1975 rule an exempt companion could engage in limitless care activities and the 20 percent limitation applied only to “general household work,” under the 2013 rule a worker subject to the exemption could only engage in “the provision of care” for a maximum of 20 percent of their weekly worktime. To justify these changes, the Department reasoned that “companionship” should be primarily focused on the provision of fellowship and protection, with a limited allowance for care, because dictionary definitions of the term “companionship” generally do not contemplate care, and because the legislative history included descriptions of exempt companions to “someone to be there and watch an older person,” or “elder sitter.”¹⁵ The preamble to the 2013 rule further asserted that allowing for a 20 percent limitation on care achieved Congressional intent that an exempt companion’s primary purpose should be watching over the individuals receiving services, while also recognizing a limited allowance for

selected tasks as a matter of practicality.¹⁶

Second, the 2013 rule precluded any third party employers (like home care agencies) from claiming the exemption for companionship services or live-in domestic service employees.¹⁷ Here, the Department reasoned that its interpretation under the 1975 rule improperly ignored the Congressional intent of the 1974 Amendments, which was to extend minimum wage and overtime protections to direct care workers engaged in this work as a vocation, as opposed to on a casual basis, and that workers employed by a third-party agency were not employed on a casual basis.¹⁸

Following the promulgation of the 2013 rule, associations representing third-party home care agencies sued the Department, asserting that the rule misinterpreted the FLSA and violated the Administrative Procedure Act. The United States District Court for the District of Columbia initially enjoined and subsequently vacated the 2013 rule’s revisions to 29 CFR 552.6 (defining companionship) and 29 CFR 552.109 (prohibiting third-party employers from claiming the exemptions).¹⁹ In its orders, the court asserted that these provisions contravened statutory intent, characterizing the 2013 rule as an attempt to “redefin[e] a 40-year-old exemption out of existence.”²⁰ The Department appealed to the United States Court of Appeals, District of Columbia Circuit, which reversed the District Court’s vacatur on August 21, 2015, concluding that the 2013 Rule was a valid exercise of the Department’s delegated rulemaking authority to interpret the section 13(a)(15) and 13(b)(21) exemptions under *Chevron* deference.²¹

The 2013 rule became effective on October 13, 2015, when the D.C. Circuit issued the mandate for its decision upholding the rule. The Department began enforcing the rule on November 12, 2015.

II. Discussion

The Department proposes to rescind the 2013 rule in its entirety and return to the 1975 regulations which were promulgated soon after the amendments

⁵ 29 U.S.C. 213(a)(15).

⁶ 29 U.S.C. 213(b)(21).

⁷ Public Law 93–259 § 29(b), 88 Stat. 76.

⁸ 29 U.S.C. 213(a)(15).

⁹ See 40 FR 7404 (Feb. 20, 1975).

¹⁰ 40 FR 7405 (codified at 29 CFR 552.6).

¹¹ 40 FR 7407 (codified at 29 CFR 552.109).

¹² See *Long Island Care at Home, LTD., v. Coke*, 551 U.S. 158 (2007).

¹³ See 78 FR 60454 (Oct. 1, 2013).

¹⁴ See 29 CFR 552.6; see also 78 FR 60463–73 (explaining the changes).

¹⁵ See 78 FR 60464 (citing 119 Cong. Reg. S24773, S24801 (daily ed. July 19, 1973) and Webster’s New World Dictionary, p. 288 (2d College Ed. 1972)).

¹⁶ See 78 FR 60457.

¹⁷ See 29 CFR 552.109.

¹⁸ See 78 FR 60482.

¹⁹ See *Home Care Association of America v. Weil*, 76 F.Supp.3d 138 (D.D.C. 2014); see also *Home Care Association of America v. Weil*, 78 F.Supp.3d 123 (D.D.C. 2015).

²⁰ 78 F.Supp.3d at 130.

²¹ See *Home Care Association of America v. Weil*, 799 F.3d 1084, 1090–96 (D.C. Cir. 2015).

to the FLSA and were in place for nearly 40 years. The Department has reviewed the 2013 regulations and now questions whether the 1975 regulations better comport with the statute and Congress's intent to exempt home care employees from FLSA coverage. Returning to the 1975 regulations would also significantly reduce regulatory burden for the consumers and providers of home care services, which in turn could help to expand access to home care services. The Department welcomes comment on these preliminary assessments. While the discussion below focuses on the two major proposed changes to 29 CFR 552.6 and 29 CFR 552.109, returning to the 1975 regulations would result in other changes to 29 CFR part 552, such as 29 CFR 552.109 concerning live-in domestic service employees. The Department invites comment on the proposal to return to the 1975 regulations in their entirety.

A. Restoring the Ability of Third-Party Employers To Claim the Section 13(a)(15) "Companionship Services" Exemption and Section 13(b)(21) Exemption for "Live-In" Domestic Service Workers

The Department is proposing to return to 1975 regulations' application of the companionship services and live-in domestic service employee exemptions to third party employers. As noted earlier, section 13(a)(15) exempts from minimum wage and overtime requirements "any employee employed in domestic service employment to provide companionship services for individuals who (because of age or infirmity) are unable to care for themselves (as such terms are defined and delimited by regulations of the Secretary)," while section 13(b) exempts from the overtime compensation requirements "any employee who is employed in domestic service in a household and who resides in such household."²² These statutory provisions do not explicitly or implicitly exclude third party employers of employees engaged in companionship services or live-in domestic service from the exemptions. While other FLSA exemptions specify employer-related exemption criteria,²³

nothing in the statutory language exempting companion workers and live-in domestic service employees suggests that third party employers are treated differently from other employers. The Department is considering whether the best interpretation of this language is that if Congress intended to narrow the exemption, it would have said so explicitly, as it has done for many other categories in the FLSA. For example, babysitters are exempt from minimum wage and overtime, but only if they are "employed on a casual basis."²⁴

Permitting third party employers to claim the companionship services exemption would be consistent with the Department's contemporaneous understanding of the 1974 FLSA Amendments.²⁵ In 1975, the Department concluded after notice-and-comment rulemaking that the new exemptions for companions and live-in domestic service workers should be available to third party employers "since these exemptions . . . apply to 'any employee' engaged 'in' the enumerated services," remarking that this interpretation would be "consistent with the statutory language and prior practices concerning other similarly worded exemptions."²⁶ In 2007, when the U.S. Supreme Court unanimously upheld the legality of the 1975 Rule's third party employer provision, the Court concluded that "more than 30 years later [this reasoning] remains a reasonable, albeit brief, explanation."²⁷

The Department acknowledges that it adopted a narrower interpretation of the section 13(a)(15) exemption in the 2013 rule, which was subsequently upheld by the U.S. Court of Appeals for the D.C. Circuit in *Home Care Association of America v. Weil*, 799 F.3d 1084 (D.C. Cir. 2015), *cert. denied*, 579 U.S. 927 (2016). However, the Department is considering the effect of a recent Supreme Court decision, *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), on the legal foundation that underpinned the Department's 2013 rule and the D.C. Circuit's subsequent approval of that rule.

In the *Loper Bright* decision issued last year, the Supreme Court eliminated "Chevron deference," a doctrine of

administrative law which previously required courts to defer to agency interpretations of ambiguous statutes so long as such interpretations were "permissible."²⁸ Going forward under *Loper Bright*, the only "permissible" interpretation of a statute is the one that courts—and not federal agencies—determine is the "best reading" of the statute.²⁹ Some employers have argued that because of *Loper Bright*, the 2013 rule's third party employer provision is no longer valid. The Department has thus far taken the position in litigation that the 2013 rule is still valid despite the 2024 *Loper Bright* decision, but is now taking a fresh look at arguments to the contrary.

In sum, the Department seeks to determine whether, with respect to third party employers, its original interpretation of the section 13(a)(15) and 13(b)(21) exemptions is the better reading of the FLSA's statutory text. The Department welcomes comment on this issue.

B. Limits on the Provision of Care by Exempt Companion Workers

As with third party employment, the Department is considering whether to restore the definition of "companionship services" reflected in the Department's pre-2013 regulations. Among other changes, the 2013 rule changed the definition from "fellowship, care, and protection" to "fellowship and protection."³⁰ The 2013 regulations permit some "care," but only up to 20 percent of the total hours worked.³¹ While the 1975 regulations wholly included "household work related to the person's care . . . such as meal preparation, bed making, washing of clothes," the 2013 regulations limited the time that could be spent on such services.

The statutory exemption applies to work done for those people who "are unable to care for themselves."³² By definition, these people need "care," not just fellowship and protection. Thus, basic meal preparation, bed making, and washing of clothes is an important part of companionship services. The Department has tentatively determined that the 1975 regulations more sensibly restricted the companionship services exemption to "those services which provide fellowship, care, and protection."³³ "Indeed, what services could possibly

²² See 29 U.S.C. 213(a)(15), 213(b)(21).

²³ See, e.g., 29 U.S.C. 13(a)(6) (exempting "any employee employed in agriculture" if, among other criteria, "such employee is employed by an employer who did not, during any calendar quarter during the preceding calendar year, use more than five hundred man-days of agricultural labor"); *id.* at 13(b)(9) (exempting "any employee employed as an announcer, news editor, or chief engineer by a radio or television station the major studio of which is located [in a low-population area]"); see also 29

U.S.C. 213(a)(1) (providing a special tolerance for the performance of nonexempt work by exempt executive and administrative employees "of a retail or service establishment").

²⁴ See 29 U.S.C. 213(a)(15).

²⁵ See *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 386 (2024) ("[T]he contemporaneous construction of those who were called upon to act under the law, and were appointed to carry its provisions into effect, is entitled to very great respect.") (citations omitted).

²⁶ 40 FR 7405.

²⁷ *Long Island Care at Home*, 551 U.S. at 175.

²⁸ *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984).

²⁹ *Loper Bright*, 603 U.S. at 400.

³⁰ 29 CFR 552.6(a).

³¹ 29 CFR 552.6(b).

³² 29 U.S.C. 213(a)(15).

³³ 40 FR 7405 (codified at 29 CFR 552.6).

be required more by those ‘unable to care for themselves’ than care itself.”³⁴ While the 1975 companionship services exemption did not include care provided by “trained personnel such as nurses,” the Department is considering whether the exemption should once again apply to “household work related to the care of the aged or infirm person such as meal preparation, bed making, washing of clothes, and other similar services.”³⁵

In the 2013 rule, the Department justified its limitation of care-related duties by analogizing exempt companions to babysitters, citing to remarks in the legislative history of the 1974 FLSA Amendments which described the role of an exempt companion to include passive activities such as “sit[ting]” and “watch[ing].”³⁶ The Department is reevaluating these arguments, cognizant that the Department’s regulations have always recognized that fellowship and protection are elements of exempt companionship services. More fundamentally, “[b]abysitters provide care—assistance with activities of daily living and instrumental activities of daily living—to the extent the children they are watching are unable to care for themselves.”³⁷ For example, babysitters are often responsible for feeding, bathing, and changing the diapers of young children, and often prepare food and drive children to places they cannot reach on their own.³⁸ While the Department has long advised that “[t]he term ‘babysitting services’ does not include services relating to the care . . . of infants or children which are performed by trained personnel, such as registered, vocational, or practical nurses,”³⁹ the regulation for casual babysitters who are exempt under section 13(a)(15) do not otherwise place any limitation on a babysitter’s provision of care. The Department now believes the regulation for exempt companions should not be any more restrictive.

Thus, the Department is proposing to restore “care” alongside “fellowship” and “protection” as an example of exempt “companionship services,” consistent with its contemporaneous interpretation of the FLSA as reflected in the 1975 Rule. The Department

welcomes comment on this proposal and the reasoning behind it.

C. Policy Considerations Germane to the Purpose of the FLSA’s Exemption for Companions and Live-In Domestic Service Employees

As discussed more fully in the regulatory impact analysis in section III(A) of this notice, the Department has tentatively determined that the 2013 rule has had negative effects on the ground which are hindering consumer access to home- and community-based services. These consequences are contrary to the policy goals that motivated Congress’ decision to include the section 13(a)(15) and 13(b)(15) exemptions in the 1974 FLSA Amendments.⁴⁰

For example, one study by the U.S. Government Accountability Office (GAO) found that home care providers and states administering Medicaid-financed home care programs responded to the 2013 rule by imposing hours restrictions for home care employees to avoid overtime costs.⁴¹ GAO elaborated that these policies “exacerbated” the challenge for consumers to obtain home care, with “a few stakeholders, including worker and consumer advocacy groups, [reporting] that some consumers have had to hire additional workers . . . making it particularly difficult to find enough workers to cover their needs.”⁴² While incentivizing employers to spread employment is one of the major policy goals of the FLSA’s overtime requirement,⁴³ Congress has enacted exemptions to the overtime requirement in occupations and industries where spreading employment is difficult, unnecessary, or otherwise undesirable, such as the FLSA’s section 13(a)(1) exemption for bona fide professional employees, which includes doctors, lawyers, and teachers.⁴⁴ As with such professional employees (particularly teachers), the shortage of

qualified workers in the home care industry⁴⁵ and the paramount importance of trust and continuity between home care workers and the individuals who they help caution against an unduly narrow reading of the FLSA’s section 13(a)(15) and 13(b)(21) exemptions.

As expected, the 2013 rule has resulted in increased costs for home care providers, such as increased recruiting, hiring, and training costs.⁴⁶ Additionally, the complicated definitions and reporting regime introduced by the 2013 rule has been burdensome to implement.⁴⁷ However, some of the expected benefits of the 2013 rule have failed to fully materialize. For example, GAO’s 2020 report concluded that hourly wages and weekly earnings for home care workers “did not significantly increase” following implementation of the 2013 rule when compared to those in occupations with similar entry requirements.⁴⁸ The turnover rate for home care workers remains stubbornly high—nearly 80 percent in 2024,⁴⁹ comparable to the range of estimates provided in the 2013 rule (spanning 44 to 100 percent).⁵⁰ And although the Department predicted in 2013 that “guarantee[ing] minimum wage and overtime compensation for home care jobs . . . will attract more workers to the home care industry,”⁵¹ growth in the home care workforce “slowed” in the years following the 2013 rule, with “the number of home care workers per 100 [individuals receiving home and community-based services] declin[ing] by 11.6 percent between 2013 and 2019.”⁵² These findings call into question whether the benefits of the 2013 rule truly exceeded its costs.

For all of the reasons discussed above, the Department proposes to amend 29 CFR part 552 by rescinding the 2013

⁴⁵ See section III(A)(3), *infra*.

⁴⁶ See GAO 21–72, *supra* n. 41, at 17.

⁴⁷ *Id.*; see also Heather Madden, *Policy Focus: Free Caregivers and Repeal the Home Care Rule*, Independent Women’s Forum 2 (May 1, 2025) (asserting that “burdensome recordkeeping requirements discourage many individuals from engaging in [in-home] caregiving”), https://www.iwf.org/wp-content/uploads/2025/04/0525PF_The-Home-Care-Rule.pdf.

⁴⁸ GAO 21–72, *supra* n. 41, at 18–20.

⁴⁹ Joyce Famakinwa, *Home Care’s Industry-Wide Turnover Rate Reaches Nearly 80%*, Home Healthcare News (July 3, 2024), <https://homehealthcarenews.com/2024/07/home-cares-industry-wide-turnover-rate-reaches-nearly-80/>.

⁵⁰ See 78 FR 60543.

⁵¹ 78 FR 60548.

⁵² Amanda R. Kreider & Rachel M. Warner, *The Home Care Workforce Has Not Kept Pace With Growth In Home and Community-Based Services*, Health Affairs, vol. 42, no. 5, p. 650 (May 2023), <https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2022.01351>.

³⁴ *Home Care Association of America*, 78 F.Supp.3d at 128, *rev’d on other grounds*, 799 F.3d 1084.

³⁵ *Id.*

³⁶ 78 FR 60464.

³⁷ See *Home Care Association of America*, 78 F.Supp.3d at 129.

³⁸ *Id.*

³⁹ 29 CFR 552.4; see also 40 FR 7405 (same).

⁴⁰ The section 13(a)(15) companionship services exemption originated from the concerns of a Louisiana constituent who wrote that extending the minimum wage to her elderly mother’s paid companion would make the companion prohibitively expensive and force the constituent to quit her job and care for her mother herself. See 19 Cong. Rec. 24,797 (1973) (statement of Sen. Dominick); see also Molly Bilken, *Healthcare in the Home: Reexamining the Companionship Services Exemption to the Fair Labor Standards Act*, 35 Colum. Hum. Rts. L. Rev. 113, 125–26 (2003) (discussing Senate floor debate over the constituent’s letter).

⁴¹ See U.S. Gov’t. Accountability Off., GAO–21–72, *Observations on the Effects of the Home Care Rule* 8 (October 2020), <https://www.gao.gov/assets/gao-21-72.pdf>.

⁴² *Id.* at 23.

⁴³ See, e.g., *Overnight Motor Transportation Co. v. Missel*, 316 U.S. 572, 577–78 (1942).

⁴⁴ See 29 U.S.C. 213(a)(1).

rule in its entirety and returning to the 1975 regulations. The Department invites public comment on this proposal and the preliminary assessments behind it. The Department specifically invites comment on whether these changes are likely to increase the supply of qualified home health workers, and whether the proposal is likely to decrease regulatory burden on home care consumers and providers.

III. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866

Under Executive Order 12866, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) determines whether a regulatory action is significant and, therefore, subject to the requirements of the Executive Order and OMB review.⁵³ Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as a regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more, or adversely affect in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as economically significant); (2) create serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. OIRA has determined that this proposed rule is economically significant under section 3(f) of Executive Order 12866.

Executive Order 13563 directs agencies to, among other things, propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; that it is tailored to impose the least burden on society, consistent with obtaining the regulatory objectives; and that, in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. Executive Order 13563 recognizes that some costs and benefits are difficult to quantify and provides that, when appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to

quantify, including equity, human dignity, fairness, and distributive impacts.

The analysis provided below outlines the impacts that the Department anticipates may result from this proposed rule and was prepared pursuant to the above-mentioned executive orders. This proposed rule is expected to be an Executive Order 14192 deregulatory action.

1. Introduction

The Fair Labor Standards Act (FLSA or Act) requires that covered, nonexempt employees be paid not less than the Federal minimum wage for all hours worked and overtime pay at one and one-half times the regular rate of pay for hours worked over 40 in a workweek. However, section 13(a)(15) of the FLSA provides an exemption from the Act's minimum wage and overtime pay requirements for "any employee employed in domestic service employment to provide companionship services for individuals who (because of age or infirmity) are unable to care for themselves."⁵⁴ Similarly, section 13(b)(21) of the FLSA provides an exemption from the Act's overtime pay requirement—but not its minimum wage requirement—for live-in domestic service workers, who are defined as "any employee who is employed in domestic service in a household and who resides in such household."⁵⁵

In this rulemaking, the Department proposes to reverse regulatory changes introduced by the 2013 final rule entitled, "Application of the Fair Labor Standards Act to Domestic Service."⁵⁶ Specifically, the Department proposes to restore the ability of third-party employers (including home care staffing agencies) to claim the FLSA's section 13(a)(15) companionship services exemption and the section 13(b)(21) exemption for live-in domestic service workers, and to eliminate limitations on "the provision of care" by employees who are exempt under the companionship services exemption.

2. Need for Rulemaking

The Department has carefully reviewed the 2013 final rule and is considering whether its pre-2013 regulations better comport with the FLSA's statutory language and Congress's intent to exempt home care employees from FLSA coverage. Returning to the Department's pre-2013 regulations could also significantly reduce regulatory burden and help to

expand access to home care services, consistent with policy goals that inform the FLSA's exemptions for companion employees and live-in domestic service employees.

3. Baseline Conditions and Affected Populations

According to available data from the Bureau of Labor Statistics (BLS), in 2023, there were approximately 3.7 million "Home Health and Personal Care Aides" employees in the United States.⁵⁷ Consistent with the methodology used to estimate the number of affected workers in the 2013 rule, the Department believes that this figure represents an upper bound estimate of the total number of home care workers "employed by agencies" who could be affected by this proposed rule.⁵⁸ The Department notes, for example, that some of these 3.7 million workers would "[remain] covered by minimum wage and overtime protections at the state level,"⁵⁹ while others might be "employed in facilities, such as nursing homes and hospitals,"⁶⁰ and therefore are not domestic service employees eligible to be classified as exempt companions or live-in domestic service employees under sections 13(a)(15) or 13(b)(21) of the FLSA. However, this estimate might not account for workers in other occupations who might be affected by this proposed rule, such as live-in nannies.⁶¹ The Department welcome feedback from the public on ways to refine this upper-bound estimate of workers employed by agencies who might be affected by this rule.

Data limitations continue to make it difficult to estimate the number of "independent providers" who might be affected by this rulemaking, *i.e.*, home care workers employed directly by a consumer or a member of the consumer's family or household.⁶² Last year, the Paraprofessional Healthcare Institute (PHI) estimated that there were "at least 1.5 million home care workers, including family members . . .

⁵⁷ See Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wages, May 2023, 31–1120 Home Health and Personal Care Aides (visited June 17, 2025), <https://www.bls.gov/oes/2023/may/oes311120.htm?utm>. This figure does not include self-employed home care workers.

⁵⁸ See 78 FR 60519–20 (adding the number of employees in BLS' then-separate occupation codes for "Home Health Aides" and "Personal Care Aides" to estimate that there were "approximately 1.75 million direct care workers employed by agencies in 2011").

⁵⁹ 78 FR 60520.

⁶⁰ *Id.*

⁶¹ See Madden, *supra* n. 47, at 4.

⁶² See 78 FR 60512 (discussing data limitations in estimating the number of independent providers potentially affected by the 2013 rule).

⁵³ See 58 FR 51735, 51741 (Oct. 4, 1993).

⁵⁴ 29 U.S.C. 213(a)(15).

⁵⁵ See 29 U.S.C. 213(b)(21).

⁵⁶ 78 FR 60454.

employed as ‘independent providers’ through Medicaid-funded consumer-direction programs, based on 2022–2023 survey data on consumer enrollment in these programs.”⁶³ The Department will use this 1.5 million figure as its upper bound estimate for the number of independent providers potentially affected by this proposed rule, keeping in mind that it includes workers who might remain covered by minimum wage and overtime requirements under state law. The Department welcomes feedback on this choice.

According to the Bureau of Labor Statistics (BLS), “home health and personal care aides” monitor the condition of people with disabilities or chronic illnesses and help them with daily living activities.⁶⁴ In addition to these general duties, “home health aides” perform basic health-related services—such as checking a client’s pulse, temperature, and respiration rate—depending on the state in which they work.⁶⁵ “Personal care aides,” sometimes called caregivers or personal attendants, are generally limited to providing nonmedical services, including companionship, cleaning, cooking, and driving.⁶⁶ The median pay for home health and personal care aides is \$16.78 per hour, with median annual earnings of \$34,900 per year.⁶⁷ According to PHI, 84 percent of home care workers are women, 67 percent are non-white, and 32 percent are immigrants.⁶⁸

The home care workforce is projected to experience rapid growth in future years to meet the demands of an aging U.S. population.⁶⁹ For example, the Bureau of Labor Statistics (BLS) has projected that the demand for “home health and personal care aide” workers will grow 21 percent from 2023 to 2033, much faster than the 4 percent average for all occupations.⁷⁰ Indeed, the home

care workforce has already doubled in size over the past ten years, growing from 1.4 million home care workers in 2014 to more than 2.9 million in 2023.⁷¹

Despite this growth, the supply of home care workers is failing to keep pace with the growing demand for home care services.⁷² According to a 2023 industry report, “the workforce shortage in home-based care has reached crisis proportions,” with “home health care providers [reporting that they turn] away over 25% of referred patients due to staff shortages.”⁷³ Although the Department predicted in the regulatory impact analysis for its 2013 rule that “guarantee[ing] minimum wage and overtime compensation for home care jobs . . . will attract more workers to the home care industry,”⁷⁴ growth in the home care workforce “slowed” in the years following the 2013 rule, resulting in “the number of home care workers per 100 [individuals receiving home and community-based services] declin[ing] by 11.6 percent between 2013 and 2019.”⁷⁵

In the absence of this rulemaking, home care workers and other live-in domestic service employees would continue to be entitled to minimum wage and overtime pay if they are employed by a “third party” employer, such as a home care agency that supplies workers in an “agency-directed model” of home care.⁷⁶ Additionally, independent providers who are currently exempt companions would likely continue spending no more than 20 percent of their weekly worktime providing “care” to the individuals they serve, which is a requirement to remain exempt under the current regulations.⁷⁷ The Department assumes that many nonexempt companion workers employed by third party employers presently spend more than 20 percent of their weekly worktime providing “care” to individuals, as the 20 percent limit on care introduced in the 2013 rule only

applies to companion workers who are exempt. The Department welcomes comment on these assumptions, which inform the baseline scenario used to measure the potential effects of this rulemaking.

4. Anticipated Benefits, Costs, and Transfers

As noted earlier, the Department assumes that there are 3.7 million home care workers employed by third-party agencies, and an additional 1.5 million home care workers employed directly by a consumer (or their family or household) who are commonly described as “independent providers.”⁷⁸ Under this proposal, some or all of the 3.7 million home care workers employed by third-party agencies could become newly exempt under the FLSA as a consequence of the proposed changes third party employment in section 552.109, but some of these workers may not be affected as a practical matter if they remain subject to minimum wage and overtime pay requirements under state law. While the estimated 1.5 million independent providers would not be affected by the proposed changes to third party employment in section 552.109, some of these workers could have greater care-giving responsibilities as a consequence of the proposed changes to the definition of “companionship services” in section 552.6—at least to the extent that these independent providers presently are (and would remain) FLSA-exempt companions.

i. Benefits

The Department expects that its proposal to revert to the pre-2013 regulations would reduce the cost of home care services by providing home care staffing agencies with greater scheduling flexibility and reduced labor costs for home care workers who become newly exempt. Relatedly, this rulemaking could obviate compliance costs related to recordkeeping and other costs for home care providers, such as increased hiring, recruiting, and training costs, that stakeholders have asserted

⁷⁸ These home care workers are “independent” in the sense that their employment is unaffiliated with a third-party provider, not that they are self-employed independent contractors. Independent providers are typically employees of the consumers they serve, or the families or households of those consumers. However, it is possible that an independent provider could be an independent contractor rather than an employee for the purposes of the FLSA. See 78 FR 60484. The Department welcomes comment on the extent to which some of the estimated 1.5 million independent providers might be independent contractors.

⁶³ PHI, *Direct Care Workers in the United States: Key Facts 2024*, 8 (2024), https://www.phinational.org/wp-content/uploads/2024/09/PHI_Key_Facts_Report_2024.pdf.

⁶⁴ See Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook: Home Health and Personal Care Aides* (April 18, 2025), <https://www.bls.gov/ooh/healthcare/home-health-aides-and-personal-care-aides.htm>.

⁶⁵ *Id.* (described in the “What They Do” tab)

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ See PHI, *supra* n. 63, at 6–7.

⁶⁹ The U.S. Census Bureau projects that in 2050, the U.S. population for individuals ages 65 and over will be 83.9 million, which is almost double what it was (43.1 million) in 2012. See U.S. Census Bureau, *An Aging Nation: The Older Population in the United States* (2014), <https://www.census.gov/library/publications/2014/demo/p25-1140.html>.

⁷⁰ U.S. Bureau of Labor Statistics, *Occupational Outlook Handbook: Home Health and Personal Care Aides* (visited June 23, 2025), <https://www.bls.gov/ooh/healthcare/home-health-aides-and-personal-care-aides.htm>.

www.bls.gov/ooh/healthcare/home-health-aides-and-personal-care-aides.htm#tab-6.

⁷¹ PHI, *supra* n. 63, at 8.

⁷² *Id.* at 5 (“[H]ome care employers continue to struggle to recruit and retain enough workers to meet escalating demand.”).

⁷³ Home Care Association of America & National Association for Home Care & Hospice, *The Home Care Workforce Crisis: An Industry Report and Call to Action 1* (March 2023), https://www.hcaoa.org/uploads/1/3/3/0/133041104/workforce_report_and_call_to_action_final_03272023.pdf.

⁷⁴ 78 FR 60548.

⁷⁵ Amanda R. Kreider & Rachel M. Warner, *The Home Care Workforce Has Not Kept Pace With Growth In Home and Community-Based Services*, *Health Affairs*, vol. 42, no. 5, p. 650 (May 2023), <https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2022.01351>.

⁷⁶ See GAO 21–72, *supra* n. 41, at 8.

⁷⁷ See 29 CFR 552.6(b).

are attributable to the 2013 rule.⁷⁹ This would result in direct costs savings for employer home care agencies and potential indirect cost savings for the consumers of home care services and for Federal and State governments, which reimburse home care services through Medicaid.⁸⁰

The Department additionally expects that this NPRM, if adopted, would expand access to home care services. By lowering labor costs, the proposed rule may encourage more providers to enter or expand operations in the home care market, increasing the availability of home care services for aging and disabled populations. Relatedly, easier access to home-based care may delay or prevent placement in more expensive institutional settings, aligning with federal and state policies favoring HCBS. Consumers who would prefer one home care worker, rather than having multiple people assist them with sensitive activities such as bathing and toilet use, would benefit from the proposed rule to the extent that it lessens incentives to spread jobs across multiple workers.

Finally, workers who are, in the baseline, employed by multiple home care agencies (working more than 40 hours per week in total) may be able to consolidate their employment with one agency, thus yielding a convenience-related benefit.

The Department welcomes comment on the likelihood of these potential benefits and the extent to which they offset or outweigh the potential costs of this rulemaking, discussed below.

ii. Costs

Under the NPRM, many home care workers presently employed by third party agencies would become newly exempt and lose the right to receive minimum wage and overtime pay under the FLSA. Losing the right to receive the federal minimum wage would not affect most workers, as the median hourly wage for home health and personal care aides was \$16.12 per hour in 2023—well above the \$7.25 per hour federal minimum wage.⁸¹ However, losing the right to receive overtime pay could result in home care workers working additional overtime hours at straight-time pay and/or receiving less pay for the overtime work they would perform in the absence of this proposed rule. These potential effects—longer work

hours and/or less pay—could negatively impact the morale of affected home care workers and lead to increased employee turnover and difficulty attracting skilled workers to the industry.⁸²

Additionally, the Department anticipates that a final rule similar to this proposal would result in modest regulatory familiarization costs. Although the proposed rule would not impose any new regulatory requirements on home care agencies or consumers that these stakeholders would need to learn about, the Department expects that home care agencies, consumers, and home care workers would choose to spend time learning about this rulemaking if it is finalized. Such familiarization costs would be modest because the effects of the proposed rule are fairly straightforward.

iii. Transfers

The proposed rule would likely result in a transfer of income from domestic workers to employers, state Medicaid programs, and private consumers. The majority of this income transfer would come from home care workers currently employed by third party employers, who could become newly exempt from minimum wage and overtime pay as a consequence of this rulemaking. This transfer is not a net cost to society but represents a redistribution of income and purchasing power.

As noted earlier, the majority of this income transfer would be attributable to avoided overtime premiums, as most of home care workers affected by this rulemaking are paid well above the FLSA's \$7.25 per hour minimum wage. The Department notes that, while it had previously anticipated significant transfers from employers to home care workers in the form of overtime earnings, GAO's 2020 report concluded that earnings "did not significantly increase" following implementation of the 2013 final rule.⁸³ This may be because the Department did not anticipate the extent to which affected employers would respond to the 2013 final rule by reducing the hours of their home care employees, thereby avoiding overtime pay and reducing regular earnings.⁸⁴ The transfer resulting from rescission of the 2013 final rule is thus likely to be more muted than the

Department's 2013 analysis suggested. This transfer effect could also be mitigated to the extent that third party home care providers respond to this rulemaking by allowing exempt home care workers to work longer hours than if such workers were nonexempt.⁸⁵ The Department welcomes comments on what transfer effects may occur in light of how employers may respond to the rescission of the 2013 final rule.

5. Discussion of Regulatory Alternatives

The Department considered two alternatives to this proposal. First, the Department considered the alternative of preserving the status quo under the current regulations. This alternative was rejected for the reasons discussed earlier in sections II and III(A)(2) of this notice. Second, the Department considered the alternative of retaining some changes from the 2013 rule in lieu of a wholesale return to the pre-2013 regulations—specifically, retaining all changes to the regulatory text in part 552 introduced by the 2013 rule *except* for the third party provision codified at 29 CFR 552.109 and limits on "the provision of care" codified in 29 CFR 552.6(b). This approach would, for example, keep the 2013 rule's updated definition of the job duties which constitute "care" and its removal of outdated domestic service worker examples like "governesses," "footmen," and "grooms." The Department invites comments on these two regulatory alternatives, as well as other regulatory alternatives that commenters may propose.

6. Conclusion

The proposed rule is anticipated to result in numerous benefits, including potentially significant reductions in the cost of obtaining and providing home care services. These benefits must be weighed against likely reductions in employee earnings and worker protections. Given these tradeoffs, the Department seeks public comment and empirical data to better quantify the proposed rule's effects (perhaps by updating quantitative inputs used in the analysis accompanying the 2013 final rule) and ensure that any final rule appropriately balances the interests of consumers, workers, and providers.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA),

⁷⁹ See GAO 21–72, *supra* n. 41, at 17.

⁸⁰ See Alice Burns, Maiss Mohamed, & Molly O'Malley Watts, *What is Medicaid Home Care (HCBS)?*, KFF (Feb. 18, 2025), <https://www.kff.org/medicaid/issue-brief/what-is-medicaid-home-care-hcbs/>.

⁸¹ See 29 U.S.C. 206(a)(1).

⁸² See Home Care Association of America, *supra* n. 76, at 5 (stating that direct care workers have a 64 percent turnover rate within their first year of hire, attributable in part to "low pay" and "burnout").

⁸³ GAO 21–72, *supra* n. 44, at 18–20.

⁸⁴ *Id.* (finding that "home care workers were less likely to work overtime following implementation of the [2013 final rule]").

⁸⁵ See GAO 21–72, *supra* n. 44, at 13 (noting that "some states restricted home care workers hours to limit overtime costs in their Medicaid programs in response to the [2013 final rule]").

hereafter jointly referred to as the RFA, requires that an agency prepare an initial regulatory flexibility analysis (IRFA) when proposing, and a final regulatory flexibility analysis (FRFA) when issuing, regulations that will have a significant economic impact on a substantial number of small entities. Because this proposed rule would have a significant (beneficial) impact on a significant number of small entities in the home care industry, the Department has prepared this IRFA.

1. Reasons Why Action by the Agency Is Being Considered and Statement of Objectives and Legal Basis for the Proposed Rule

The FLSA generally requires that employees be paid at least the Federal minimum wage, currently \$7.25 per hour, for every hour worked and at least one and one-half times their regular rate of pay for each hour worked over 40 in a single workweek. 29 U.S.C. 206(a), 207(a). Prior to 1974, the FLSA's minimum wage and overtime compensation provisions did not apply to domestic service workers. In 1974, Congress revised the FLSA to extend coverage to all domestic service workers, however, Congress included an exemption from the minimum wage and overtime compensation requirements for domestic service workers who provide "companionship services" and an exemption from the overtime compensation requirement for live-in domestic service workers. In 1975, the Department promulgated regulations implementing the companionship and live-in domestic service employee exemptions. These regulations defined companionship services as "fellowship, care, and protection," which included "household work . . . such as meal preparation, bed making, washing of clothes, and other similar services" and could include other general household work not exceeding "20 percent of the total weekly hours worked." Additionally, the 1975 regulations permitted third party employers, or employers of home care workers other than the individuals receiving care or their families or households, to claim both the companionship services and live-in domestic service employee exemptions.

In 2013, the Department revised its companionship services and live-in employee regulations. The 2013 regulations defined "companionship services" narrowly to encompass only workers providing limited, non-professional services. And the regulations precluded third party employers (like home care agencies) from claiming the exemption for

companionship services or live-in domestic service employees.

The Department proposes to rescind the 2013 regulations and restore the 1975 standards that applied following the amendments to the FLSA. 29 CFR part 552. The Department is also requesting comment on reasons to keep or rescind the 2013 home care regulations, the best definition of companionship services, and whether third party employers should be covered by the exemption under the best reading of the FLSA. The Department also seeks comment on the 2013 regulations' consistency with statutory authority, and costs and benefits.

2. Description of the Number of Small Entities to Which the Recission Will Apply

The 2013 regulation defines a "small entity" as a (1) small not-for-profit organization, (2) small governmental jurisdiction, or (3) small business. The Department used standards defined by SBA to classify entities as small for the purpose of this analysis. For the two industries that are the focus of this analysis, the SBA defines a small business as one that has average annual receipts of less than \$19 million for Home Health Care Services (HHCS, NAICS 621610) and \$15 million for Seniors and Elderly Persons with Disabilities (SEPD, NAICS 624120). Based on the 2022 Statistics of U.S. Businesses (SUSB) data, there are 27,140 small businesses in the HHCS industry (96 percent of all business), and 32,899 small business in the SEPD industry (96 percent of all business). Thus, this rulemaking could impact 60,039 small businesses.

3. Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

There are no reporting or recordkeeping requirements associated with this rescission. Thus, the only direct costs to affected entities would be rule familiarization costs.

4. Relevant Federal Rules Duplicating, Overlapping, or Conflicting With the Proposed Rule

The Department is unaware of any Federal rules which duplicate, overlap, or conflict with the proposed rule.

5. Discussion of Regulatory Alternatives

The Department considered two alternatives to this proposal. First, the Department considered the alternative of preserving the status quo under the current regulations. This alternative was rejected for the reasons discussed earlier in sections II and III(A)(2) of this notice.

Second, the Department considered the alternative of retaining some changes from the 2013 rule in lieu of a wholesale return to the pre-2013 regulations—specifically, retaining all changes to the regulatory text in part 552 introduced by the 2013 rule except for the third party provision codified at 29 CFR 552.109 and limits on "the provision of care" codified in 29 CFR 552.6(b). This approach would, for example, keep the 2013 rule's updated definition of the job duties which constitute "care" and its removal of outdated domestic service worker examples like "governesses," "footmen," and "grooms." The Department welcomes comment on these regulatory alternatives, particularly regarding whether the Department should retain any changes from the 2013 rule which are not implicated by the legal and policy considerations motivating this rulemaking.

C. Review Under the Paperwork Reduction Act

The purpose of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*, includes minimizing the paperwork burden on affected entities. The PRA requires certain actions before an agency can adopt or revise a collection of information, including publishing for public comment a summary of the collection of information and a brief description of the need for and proposed use of the information.

As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program to provide the public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the PRA. *See* 44 U.S.C. 3506(c)(2)(A). This activity helps to ensure that the public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

A Federal agency may not conduct or sponsor a collection of information unless it is approved by the Office of Management and Budget (OMB) under the PRA and it displays a currently valid OMB control number. The public is also not required to respond to a collection of information unless it displays a currently valid OMB control number. In addition, notwithstanding any other provisions of law, no person

will be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number (44 U.S.C. 3512).

This rulemaking potentially affects the existing information collection designated as OMB Control Number 1235-0018, *Records to be kept by Employers—Fair Labor Standards Act*. Any changes to this collection will be communicated through an upcoming 60-day **Federal Register** Notice.

D. Review Under Executive Order 13132

E.O. 13132, “Federalism,” 64 FR 43255 (August 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.

The Department has examined this proposed rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Review Under the Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104-4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. 2 U.S.C. 1532(a), (b)). The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a “significant intergovernmental mandate,” and requires an agency plan

for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them.

The Department examined this proposed rule according to UMRA and its statement of policy and determined that the rule does not contain a Federal intergovernmental mandate, nor is it expected to require expenditures of \$100 million or more (adjusted for inflation) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector. As a result, the analytical requirements of UMRA do not apply.

J. Review Under Additional Executive Orders and Presidential Memoranda

This proposed rule is expected to be an Executive Order 14192 deregulatory action. It also implements Presidential Memorandum *Directing the Repeal of Unlawful Regulations*, dated April 9, 2025.

List of Subjects in 29 CFR Part 552

Minimum wages; Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department is proposing to amend part 552 of chapter V, subchapter A of title 29 of the Code of Federal Regulations, as set forth below:

PART 552—APPLICATION OF THE FAIR LABOR STANDARDS ACT TO DOMESTIC SERVICE

■ 1. The authority citation for part 552 continues to read as follows:

Authority: 29 U.S.C. 213(a)(15), (b)(21), 88 stat. 62; Sec. 29(b) of the Fair Labor Standards Act Amendments of 1974 (Pub. L. 93-259, 88 Stat. 76).

■ 2. Revise § 552.3 to read as follows:

§ 552.3 Domestic service employment.

As used in section 13(a) (15) of the Act, the term “domestic service employment” refers to services of a household nature performed by an employee in or about a private home (permanent or temporary) of the person by whom he or she is employed. The term includes employees such as cooks, waiters, butlers, valets, maids, housekeepers, governesses, nurses, janitors, laundresses, caretakers, handymen, gardeners, footmen, grooms, and chauffeurs of automobiles for family use. It also includes babysitters employed on other than a casual basis. This listing is illustrative and not exhaustive.

■ 3. Revise § 552.6 to read as follows:

§ 552.6 Companionship services.

As used in section 13(a)(15) of the Act, the term “companionship services” shall mean those services which provide fellowship, care, and protection for a person who, because of advanced age or physical or mental infirmity, cannot care for his or her own needs. Such services may include household work related to the care of the aged or infirm person such as meal preparation, bed making, washing of clothes, and other similar services. They may also include the performance of general household work; Provided however, That such work is incidental, *i.e.*, does not exceed 20 percent of the total weekly hours worked. The term “companionship services” does not include services relating to the care and protection of the aged or infirm which require and are performed by trained personnel, such as a registered or practical nurse. While such trained personnel do not qualify as companions, this fact does not remove them from the category of covered domestic service employees when employed in or about a private household.

■ 4. Amend § 552.101 by revising the first three sentences of paragraph (a) to read as follows:

§ 552.101 Domestic service employment.

(a) The definition of “domestic service employment” contained in § 552.3 is derived from the regulations issued under the Social Security Act (20 CFR 404.1027(j)) and from “the generally accepted meaning” of the term. Accordingly, the term includes persons who are frequently referred to as “private household workers.” See S. Rep. 93-690, p. 20. The domestic service must be performed in or about the private home of the employer whether that home is a fixed place of abode or a temporary dwelling as in the case of an individual or family traveling on vacation.

■ 5. Amend § 552.102 by revising paragraph (b) to read as follows:

§ 552.102 Live-in domestic service employees.

(b) Where there is a reasonable agreement, as indicated in (a) above, it may be used to establish the employee’s hours of work in lieu of maintaining precise records of the hours actually worked. The employer shall keep a copy of the agreement and indicate that the employee’s work time generally coincides with the agreement. If it is found by the parties that there is a significant deviation from the initial agreement, a separate record should be kept for that period or a new agreement

should be reached that reflects the actual facts.

■ 6. Amend § 552.109 by revising paragraphs (a) and (c) to read as follows:

§ 552.109 Third party employment.

(a) Employees who are engaged in providing companionship services, as defined in § 552.6, and who are employed by an employer or agency other than the family or household using their services, are exempt from the Act's minimum wage and overtime pay requirements by virtue of section 13(a)(15). Assigning such an employee to more than one household or family in the same workweek would not defeat the exemption for that workweek, provided that the services rendered during each assignment come within the definition of companionship services

* * * * *

(c) Live-in domestic service employees who are employed by an employer or agency other than the family or household using their services are exempt from the Act's overtime requirements by virtue of section 13(b)(21). This exemption, however, will not apply where the employee works only temporarily for any one family or household, since that employee would not be "residing" on the premises of such family or household.

■ 8. Amend § 552.110 by revising paragraphs (b), (c), and (d) and removing paragraph (e) to read as follows:

§ 552.110 Recordkeeping requirements.

(b) In the case of an employee who resides on the premises, records of the actual hours worked are not required. Instead, the employer may maintain a copy of the agreement referred to in § 552.102. The more limited recordkeeping requirement provided by this subsection does not apply to third party employers. No records are required for casual babysitters.

(c) Where a domestic service employee works on a fixed schedule, the employer may use a schedule of daily and weekly hours that the employee normally works, and either the employer or the employee may (1) indicate by check marks, statement or other method that such hours were actually worked, and (2) when more or less than the scheduled hours are worked, show the exact number of hours worked.

(d) The employer may require the domestic service employee to record the hours worked and submit such record to the employer.

Dated: June 27, 2025.

Donald Harrison,

Acting Administrator, Wage and Hour Division.

[FR Doc. 2025–12316 Filed 6–30–25; 8:45 am]

BILLING CODE 4510–27–P

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Parts 775, 776, 779, 782, 783, 784, 789, 793, and 794

RIN 1235–AA52

Statements of General Policy or Interpretation Not Directly Related to Regulations

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Notice of proposed rule; request for comments.

SUMMARY: The Department of Labor (Department) proposes to remove parts located in Title 29, Chapter V, Subchapter B of the Code of Federal Regulations (CFR) that were not originally issued, or subsequently amended, through notice-and-comment rulemaking. Because these parts consist of interpretive rules and policy statements regarding the Fair Labor Standards Act (FLSA) which do not carry the force and effect of law, the Department believes that these parts, to the extent that they have not benefitted from public comment, should be repurposed as sub-regulatory guidance. The Department seeks comment on what provisions in Subchapter B should be retained in the CFR, as well as what kind of sub-regulatory guidance the Department should use to preserve interpretive rules and policy statements that are removed from the CFR. This summary can be found at <https://www.regulations.gov> by searching by the RIN: 1235–AA52.

DATES: Comments must be received on or before August 1, 2025.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 1235–AA52, by either of the following methods:

- *Electronic Comments:* Submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Address written submissions to: Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210.

Instructions: Response to this notice of proposed rulemaking (NPRM) is voluntary. The Department requests that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this NPRM. Commenters submitting file attachments on <https://www.regulations.gov> are advised that uploading text-recognized documents—*i.e.*, documents in a native file format or documents which have undergone optical character recognition (OCR)—enable staff at the Department to more easily search and retrieve specific content included in your comment for consideration.

Anyone who submits a comment (including duplicate comments) should understand and expect that the comment, including any personal information provided, will become a matter of public record and will be posted without change to <https://www.regulations.gov>. The Department posts comments gathered and submitted by a third-party organization as a group under a single document ID number on <https://www.regulations.gov>. All comments must be received by 11:59 p.m. ET on August 1, 2025, for consideration in this rulemaking; comments received after the comment period closes will not be considered.

The Department strongly recommends that commenters submit their comments electronically via <https://www.regulations.gov> to ensure timely receipt prior to the close of the comment period. Please submit only one copy of your comments by only one method.

Docket: Go to the Federal eRulemaking Portal at <https://www.regulations.gov> for access to the rulemaking docket, including any background documents and the plain-language summary of the rule of not more than 100 words in length required by the Providing Accountability Through Transparency Act of 2023.

FOR FURTHER INFORMATION CONTACT: Daniel Navarrete, Director, Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–0406 (this is not a toll-free number). Alternative formats are available upon request by calling 1–866–487–9243. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

Questions of interpretation or enforcement of the agency's existing regulations may be directed to the nearest WHD district office. Locate the

nearest office by calling the WHD's toll-free help line at (866) 4US-WAGE ((866) 487-9243) between 8 a.m. and 5 p.m. in your local time zone, or log onto WHD's website at <https://www.dol.gov/agencies/whd/contact/local-offices> for a nationwide listing of WHD district and area offices.

SUPPLEMENTARY INFORMATION:

I. Background

The Administrative Procedure Act (APA) broadly defines the term “rule” as “[t]he whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency[.]” 5 U.S.C. 551(4). Within this category are “legislative rules” which have “the force and effect of law,” *Perez v. Mortgage Bankers Assoc.*, 575 U.S. 92, 96 (2015),¹ and “interpretive rules,” which “advise the public of the agency’s construction of the statutes and rules which it administers” but “do not have the force and effect of law and are not accorded that weight in the adjudicatory process.” *Id.* at 97 (internal quotation marks omitted). The APA also recognizes a third kind of rule: “general statements of policy,” 5 U.S.C. 553, which are understood to be “agency statements of general applicability, not binding on members of the public, ‘issued . . . to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.’”²

Since the Code of Federal Regulations (CFR) was created in 1937, Federal law has described the CFR as “a complete codification of the documents of each agency of the Government having general applicability and legal effect,” which are “relied upon by the agency as authority for, or are invoked or used by it in the discharge of, its activities or functions.” 44 U.S.C. 1510(a) (emphasis added); *see also* 1 CFR 8.1 (describing the CFR as “a compact and practical code . . . contain[ing] each Federal

regulation of general applicability and legal effect”). Similarly, Executive Order 12866—which sets forth Presidential oversight of the Federal regulatory process—defines the term “regulation” in relevant part as “an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law[.]” 58 FR 51735, 51737 (Sept. 30, 1993). These authorities imply, and can lead the general public to infer, that all “regulations” codified in the CFR are legislative rules with the force and effect of law.

Legislative rules set forth by the Department’s Wage and Hour Division (WHD) regarding the Fair Labor Standards Act (FLSA) primarily appear in Subchapter A of its assigned chapter in the CFR. *See* 29 CFR parts 500–697. Examples of legislative rules issued by WHD include employer recordkeeping requirements established pursuant to section 11(c) of the FLSA (located at 29 CFR part 516),³ criteria which “define and delimit” the FLSA’s section 13(a)(1) exemption for executive, administrative, and professional employees (located at 29 CFR part 541),⁴ and child labor regulations issued under section 3(l) of the FLSA (located at 29 CFR part 570).⁵ Regulations on topics addressed in certain FLSA amendments, such as the FLSA’s application to tipped employees (located at 29 CFR part 531 subpart D) or the employees of state or local governments (located at 29 CFR part 553), are also legally binding legislative rules.⁶

However, since the 1940s, WHD has provided “Statements of General Policy or Interpretations Not Directly Related to Regulations” in Subchapter B of its assigned CFR chapter,⁷ which presently spans parts 775 to 795 of Title 29. Most of the parts in Subchapter B provide

interpretive guidance on topics that Congress has not specifically delegated rulemaking authority to the Department to address, such as: the principles of coverage under the FLSA (29 CFR part 776); the determination of an employee’s “regular rate of pay” used to calculate overtime premiums under the FLSA (29 CFR part 778); the definition of “hours worked” under the FLSA (29 CFR part 785); or independent contractor status under the FLSA (29 CFR part 795). While some of the parts or provisions located in Subchapter B were originally issued or subsequently amended through notice-and-comment rulemaking, many were not, as the APA exempts “interpretative rules” and “general statements of policy” from the notice-and-comment requirement that generally applies to legislative rules. *See* 5 U.S.C. 553(b)(A).

Like other forms of guidance, the interpretive rules and policy statements in Subchapter B provide “enormous value” by “channel[ing] the discretion of agency employees, increas[ing] efficiency, and enhanc[ing] fairness by providing the public clear notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties.”⁸ “[W]hile not controlling upon the courts,” interpretive rules and policy statements “constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance[.]” with the weight afforded to such guidance “depend[ing] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.” *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). As with legislative rules, employers can rely upon interpretive rules and policy statements issued by the WHD Administrator under section 10 of the Portal-to-Portal Act of 1947, which provides a defense against liability for violations of the FLSA, the Walsh-Healey Public Contracts Act, or the Davis-Bacon Act for any acts or omissions that an employer makes in good faith reliance on such guidance. *See* 29 U.S.C. 259; *see also* 29 CFR 790.13–.19 (elaborating on the requirements for a “good faith reliance” defense under the Portal-to-Portal Act).

However, when interpretive rules and policy statements are codified in the CFR alongside legislative rules, there is

¹ The Supreme Court has advised that legislative rules which “carry the force and effect of law” are those which: (1) “affect[] individual rights and obligations”; (2) are “rooted in a grant of [legislative] power by the Congress;” and (3) are “promulgat[ed] . . . [in] conform[ity] with any procedural requirements imposed by Congress.” *Chrysler Corp. v. Brown*, 441 U.S. 281, 302–03 (1979) (internal quotation marks omitted).

² Admin. Conf. of the U.S., Recommendation 2017–5, *Agency Guidance Through Policy Statements* 1 (Dec. 14, 2017) (quoting Attorney General’s Manual on the Administrative Procedure Act 30 n.3 (1947)), https://www.acus.gov/sites/default/files/documents/Recommendation%202017-5%20%28Agency%20Guidance%20Through%20Policy%20Statements%29_2.pdf.

³ *See* 29 U.S.C. 211(c) (requiring employers to “make, keep, and preserve such records as [WHD] shall prescribe by regulation or order as necessary or appropriate for the enforcement of the [FLSA]”).

⁴ *See* 29 U.S.C. 213(a)(1) (exempting “any employee employed in a bona fide executive, administrative, or professional capacity . . . as such terms are defined and delimited from time to time by regulations”).

⁵ *See* 29 U.S.C. 203(l) (requiring the Department to “provide by regulation or by order” conditions of employment that would or would not constitute “oppressive child labor”).

⁶ *See* Public Law 89–601, sec. 602, 80 Stat. 830, 844 (1966) (authorizing the Department to issue regulations implementing the 1966 FLSA Amendments, including statutory provisions affecting tipped employees); *see also* Public Law 99–150, sec. 6, 99 Stat. 787, 790 (1985) (authorizing the Department to issue regulations implementing the 1985 FLSA Amendments, which addressed the FLSA’s application to the employees of state and local governments).

⁷ *See* 11 FR 14099 (Dec. 5, 1946) (adding Subchapter B).

⁸ Final Bulletin for Agency Good Guidance Practices, OMB Bull. No. 07–02, 2 (Jan. 18, 2007), https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2007/m07-07.pdf.

a risk that regulated entities and members of the public may misunderstand the nature of these materials. For example, employers may mistakenly assume that all “regulations” set forth in the CFR carry the force of law. In fact, Federal courts have sometimes stated that heightened standards of judicial deference intended for legislative rules apply to the interpretive rules set forth in Subchapter B.⁹ For example, in ruling against a plaintiff employee in *Kavanagh v. Grand Union Co., Inc.*, 192 F.3d 269 (2d Cir. 1999), the Second Circuit said that it was “not free to disregard” an interpretive rule on compensable time set forth in part 785, “when that regulation represents a permissible construction of the statute” at the time under the then-applicable *Chevron* deference. Despite remarking that “[the employee’s] situation strikes us as inequitable,” the court emphasized that “constraints on the judicial function” determined the outcome of the case. *Id.* at 272–73. Whether by courts or employers, undue deference to the guidance set forth in Subchapter B is a foreseeable outcome of authorities implying that all content in the CFR has binding “legal effect,” as noted earlier. See 44 U.S.C. 1510(a); see also 1 CFR 8.1.

Even if employers understand that the interpretive rules and policy statements set forth in Subchapter B are non-binding—i.e., that the “correctness an interpretation . . . can be determined finally and authoritatively only by the courts” and that WHD “will receive and consider statements suggesting change of any interpretation,” 29 CFR 790.1(c)—employers may feel compelled to comply with such guidance as a practical matter. As the Administrative Conference of the United States (ACUS) has noted, “modern regulatory schemes often have structural features that tend to lead

regulated parties to follow [an interpretive rule or policy statement] even if in theory they might be legally free to choose a different course, because the costs and risks associated with doing so are simply too high,” particularly where “statutes or regulations . . . subject the regulated party to the possibility of enforcement proceedings that entail prohibitively high costs regardless of outcome, or can lead to sanctions so severe that the party will not risk forcing an adjudication of the accusation.”¹⁰

This rulemaking seeks to address such risks by proposing to remove all parts from Subchapter B which have not undergone notice-and-comment rulemaking. Ensuring that all of the parts in Subchapter B have undergone notice-and-comment rulemaking will confirm that the guidance provided therein has benefited from the input of interested outside stakeholders, particularly “parties [who] lack the opportunity and resources to participate in the individual adjudicatory or enforcement proceedings to which [an interpretive rule or] policy may apply.”¹¹ The Department also intends for this action to reinforce the distinction between such rules and other sub-regulatory guidance, thereby promoting consistency in its regulatory program.

The Department acknowledges that there may once have been reason to publish interpretive guidance in the CFR at a time when few would have access to view such guidance otherwise. Indeed, when the Department began moving interpretive guidance from earlier “Interpretive Bulletins” into the CFR in the late 1940s, the Department explained that the purpose of codification was “to make available in one place interpretations of the Administrator which will provide ‘a practical guide to employers and employees as to how the office representing the public interest in enforcement of the law will seek to apply it.’” 13 FR 419, 420 (Jan. 30, 1948) (citing *Skidmore*, 323 U.S. at 138).

However, technology has widened the availability of resources available to the public, which are no longer limited to

the U.S. Code and the CFR. Indeed, it is commonplace today for interested parties to view the Department’s website and, in particular, WHD’s Field Operations Handbook (FOH), which summarizes many of the agency’s positions and cross-references to various other resources.¹² And while one of the original reasons for the CFR was to have a comprehensive publication of every agency’s rules and legal interpretations, many agencies, including WHD, issue sub-regulatory guidance outside of the CFR which is entitled to the same weight as interpretive rules and policy statements that are in the CFR.

Accordingly, the Department intends to temporarily retain all content which is removed from the CFR as sub-regulatory guidance, apart from the provisions in part 779 which are obviously obsolete.¹³

In sum, to better serve the public and increase transparency, the Department proposes to remove all interpretive rules and policy statements located in Title 29, Chapter V, Subchapter B of the CFR that have not, at least in part, been issued or revised through notice-and-comment rulemaking, while seeking comment on whether any portions should be retained in the CFR. The Department intends to relocate the removed Subchapter B provisions (other than obsolete content in Part 779) into an appendix to the FOH (with similar citations) until such time that WHD can determine which are appropriate to: (1) propose as legislative or interpretative regulations; (2) retain as sub-regulatory interpretive guidance; or (3) amend or eliminate for one or more substantive reasons. Any substantive changes made as described in category (3) would not require public notice and, as such, it would be up to the Department’s discretion regarding how to proceed with respect to any changes once the material is located in the FOH.

The Department emphasizes that this rulemaking is not a commentary on the underlying merits of any provisions

⁹ See, e.g., *Josendis v. Wall to Wall Residence Repairs, Inc.*, 662 F.3d 1292, 1299 (11th Cir. 2011) (advising that *Chevron* deference generally applies to “interpretive regulations” addressing individual and enterprise coverage under the FLSA in part 776); see also *Scott v. City of New York*, 592 F.Supp.2d 386, 398 (S.D.N.Y. 2008) (“Regardless of whether [CFR provisions addressing overtime pay] are labeled as ‘regulations’ or ‘interpretations,’ they are entitled to *Chevron* deference.”). Although *Chevron* deference was abolished last year in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2014), decisions applying *Chevron* to Subchapter B provisions were in tension with earlier Supreme Court precedent emphasizing that courts are “not required to give effect to an interpretative regulation.” *Batterton v. Francis*, 432 U.S. 416, 425 n.9 (1977) (citing *Skidmore*, 323 U.S. at 140); see also *Christensen v. Harris Co.*, 529 U.S. 576, 587 (2000) (holding that “interpretations . . . which lack the force of law . . . do not warrant *Chevron*-style deference”).

¹⁰ Recommendation 2017–5, *supra* n. 2, at 4; see also Admin. Conf. of the U.S., Recommendation 2019–1, *Agency Guidance Through Interpretive Rules* 5 (June 13, 2019) (asserting that “factors [which] deter affected persons from contesting guidance documents with which they disagree . . . operate in approximately the same manner regardless of whether a policy statement or interpretive rule is involved”), <https://www.acus.gov/sites/default/files/documents/Agency%20Guidance%20Through%20Interpretive%20Rules%20CLEAN%20FINAL%20POSTED.pdf>.

¹¹ Recommendation 2017–5, *supra* n. 2, at 6.

¹² The FOH does not establish a binding legal standard on the public and is not a device for establishing interpretive policy. Rather, the FOH is an “operations manual” that makes available to WHD investigators and staff policies already “established through changes in legislations, regulations, significant court decisions, and the decisions and opinions of the WHD Administrator.” Field Operations Handbook, U.S. Dept. of Labor (last accessed June 9, 2025), <https://www.dol.gov/agencies/whd/field-operations-handbook>; see also WHD Opinion Letter FLSA2020–12, at 4 (Aug. 31, 2020); *Probert v. Family Centered Servs. of Alaska, Inc.*, 651 F.3d 1007, 1012 (9th Cir. 2011).

¹³ Most of the provisions in Part 779 were last updated in 1970, see 35 FR 5856 (Apr. 9, 1970), and much of this content is either obsolete or erroneous. For example, Part 779 includes numerous references to statutory language which has since been amended or repealed, as well as erroneous dollar thresholds.

which are presently located in Subchapter B. Relocating interpretive guidance from Subchapter B of the CFR to the FOH would not have any substantive import for the guidance itself, nor would the relocation invalidate or call into question any (1) WHD opinion letters, fact sheets, or other compliance assistance materials that interpret and rely on the CFR provisions, (2) any court decisions that have relied on such provisions, or (3) any of the Department's enforcement efforts that may involve these provisions.

Although it is not necessary to issue an NPRM for the relocation or elimination of individual interpretative rules or policy statements which themselves were not promulgated or revised through notice and comment rulemaking, given the scope of the proposed changes to Subchapter B, and as a matter of public courtesy, the Department is seeking comment on the current proposed rule. The Department, however, reserves its right to decline additional notice-and-comment for any future changes to content removed from the CFR as a consequence of this rulemaking.¹⁴

II. Discussion

WHD's assigned portion of the CFR (located in Chapter V of Subtitle B of Title 29) is divided into the following four subchapters: Subchapter A ("Regulations"); Subchapter B ("Statements of General Policy or Interpretation Not Directly Related to Regulations"); Subchapter C ("Other Laws"); and Subchapter D ("Garnishment of Earnings"). The potential effects of this rulemaking for each of these sections is addressed below.

A. The Status of Subchapters A, C, and D

Subchapter A ("Regulations") contains Part 500 through Part 697. To the extent that these parts contain provisions that should be removed or relocated, such provisions may be addressed in a separate rulemaking. To provide one illustration, Part 531 ("Wage Payments Under the Fair Labor Standards Act of 1938") contains a subpart (Subpart C) entitled "Interpretations," consisting of what appear to be non-binding interpretive rules. For example, an introductory section to Subpart C of part 531 explains that the "the interpretations [provided in this subpart] indicate . . . the

construction of the law which the Secretary of Labor and the [WHD] Administrator *believe* to be correct and which will guide them in the performance of their administrative duties under the [FLSA] unless and until they are otherwise directed by *authoritative decisions of the courts.*" 29 CFR 531.25(b) (emphases added). Nearly identical language appears in an introductory section for 29 CFR part 790, which provides interpretive guidance about the Portal-to-Portal Act of 1947. *See* 29 CFR 790.1(c).

If Subpart C of part 531 consists of non-binding "Interpretations," it arguably should not appear alongside legislative rules in a part located within Subchapter A ("Regulations"). By contrast, if the provisions in Subpart C of part 531 should be regarded as legislative rules with the force and effect of law, then the title of Subpart C and the Introductory Statement published at 29 CFR 531.25 should be revised accordingly.

Subchapters C and D of WHD's CFR chapter may also contain non-binding interpretive rules and policy statements. *See, e.g.,* 29 CFR part 870, subpart B ("Determinations and Interpretations"). However, as with provisions located in Subchapter A, content which is located within Subchapters C and D is outside the scope of this rulemaking.

B. The Status of Subchapter B

Part 775 through Part 795 are contained in Subchapter B, "Statements of General Policy or Interpretation Not Directly Related to Regulations." On its face, Subchapter B features non-binding interpretive rules and policy statements. For all of the reasons described earlier, the Department is proposing to remove all parts in Subchapter B that were not, at least in part, promulgated through notice-and-comment rulemaking from the CFR. Except for content which is obviously outdated or erroneous,¹⁵ the Department proposes to relocate these provisions to WHD's FOH as appended "Interpretive Bulletins" which use the same section numbers as currently used in the CFR. Importantly, the provisions being relocated for purposes of clarity rather than removed for purposes of obsolescence would continue to constitute the Department's sub-regulatory position. The Department seeks comment on this proposal, including whether appending Interpretive Bulletins to the FOH would be an appropriate means of preserving interpretive rules and policy statements that are removed from the CFR or

whether the Department should consider alternative sub-regulatory guidance vehicles, such as Field Assistance Bulletins (FABs) or Administrator Interpretations (AIs).

As noted earlier, some parts in Subchapter B were initially issued or subsequently amended through notice-and-comment rulemaking. Specifically, the Department has engaged in notice-and-comment rulemaking to issue or amend provisions in parts 778,¹⁶ 780,¹⁷ 785,¹⁸ 786,¹⁹ 788,²⁰ 790,²¹ and 795.²² The Department proposes to retain these parts in their entirety for legibility reasons and because the public has had the opportunity to request changes in these parts in at least one prior rulemaking. Relatedly, the Department proposes to rename Subchapter B as "Other Regulations." The Department seeks comment on this approach, including whether the Department should instead retain in the CFR only those parts which have been revised in a comprehensive rulemaking (*e.g.,* retaining part 778 while removing part 785), or only those provisions which have been addressed in a notice-and-comment rulemaking.

Given the number of provisions within Subchapter B that may be impacted under this proposal, as a matter of public courtesy, the Department seeks comment on the proposed rule. The Department, however, recognizes that interpretive rules are not subject to the APA's notice and comment requirements which typically apply to legislative rules. As such, the Department reserves the right to decline additional notice-and-comment for any future changes to content removed from the CFR as a consequence of this rulemaking.

III. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866

Under Executive Order 12866, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) determines whether a regulatory action is significant and, therefore, subject to the

¹⁶ *See* 84 FR 68736 (2019 rule revising numerous provisions); 85 FR 34970 (2020 rule revising 778.114).

¹⁷ *See* 76 FR 18832 (2011 rule revising 780.400, 780.401, 780.406, and 780.408); 89 FR 1638 (2024 rule revising 780.330).

¹⁸ *See id.* (revising 785.7, 785.9, 785.34, and 785.50).

¹⁹ *See id.* (revising 786.300 and 786.350).

²⁰ *See* 89 FR 1638 (revising 788.16).

²¹ *See* 76 FR 18832 (revising 790.3).

²² *See* 89 FR 1638 (revising the entirety of part 795).

¹⁴ *See* *Perez v. Mortgage Bankers Assoc.*, 575 U.S. at 100 ("[The APA's] exemption of interpretive rules from the notice-and-comment process is categorical[.]").

¹⁵ *See, e.g., supra* n. 13 (discussing outdated and erroneous content in 29 CFR part 779).

requirements of the Executive Order and OMB review.²³ Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as a regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more, or adversely affect in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as economically significant); (2) create serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. OIRA has determined that this proposed rule is significant under section 3(f) of Executive Order 12866.

Executive Orders 12866 and 13563 direct agencies to, among other things, propose or adopt a significant rule only upon a reasoned determination that its benefits justify its costs; that it is tailored to impose the least burden on society, consistent with obtaining the regulatory objectives; and that, in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. Executive Order 13563 recognizes that some costs and benefits are difficult to quantify and provides that, when appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

The analysis provided below outlines the impacts that the Department anticipates may result if this proposed rule is finalized as proposed and was prepared pursuant to the above-mentioned executive orders. This proposed rule is expected to be an Executive Order 14192 deregulatory action.

1. Introduction

Subchapter B of WHD’s assigned CFR chapter contains non-binding interpretive rules and general policy statements issued under the Fair Labor Standards Act (FLSA), Portal-to-Portal Act, and related statutes. Many of these provisions were codified between the 1940s and 1970s without notice-and-comment procedures.

Although they are not legally binding legislative rules, the codification of these interpretive materials in the CFR may give rise to regulatory confusion. Regulated entities may mistake these statements as being legally binding legislative rules or fail to distinguish them from legally binding legislative rules in Subchapter A.

The Department therefore proposes to remove the 9 identified parts from Subchapter B. These parts were never subject to public comment. The Department intends that interpretive content other than provisions in Part 779 which are outdated or erroneous would be retained in WHD’s Field Operations Handbook (FOH) as appended Interpretive Bulletins, but welcomes comment on what kind of sub-regulatory guidance the Department should use to preserve interpretive rules and policy statements that are removed from the CFR.

Under this proposed rule, the following Subchapter B parts would remain in Title 29 of the CFR: Part 778 (“Overtime Compensation”); Part 780 (“Exemptions Applicable to Agriculture, Processing of Agricultural Commodities, and Related Subjects Under the Fair Labor Standards Act”); Part 785 (“Hours Worked”); Part 786 (“Miscellaneous Exemptions and Exclusions from Coverage”); Part 788 (“Forestry or Logging Operations in Which Not More than Eight Employees Are Employed”); Part 790 (“General Statement as to the Effect of the Portal-to-Portal Act of 1947 on the Fair Labor Standards Act of 1938”); Part 795 (“Employee or Independent Contractor Classification Under the Fair Labor Standards Act”). These parts have benefited from prior public input and retain standalone value as complete, legible documents.

2. Need for Rulemaking

As explained in greater detail in section I of this notice, the need for this rulemaking arises from the Department’s interest in: (1) reducing potential confusion between binding and non-binding rules; (2) promoting greater stakeholder engagement with WHD’s interpretive guidance; and (3) ensuring procedural integrity and transparency in regulatory design.

This NPRM is also consistent with the Department’s obligations under Executive Order 13563 to “promote predictability,” “reduce uncertainty,” and “use the best, most innovative, and least burdensome tools for achieving regulatory ends.”²⁴

3. Affected Entities

This rule does not impose compliance obligations or require behavioral changes from any regulated parties. However, it may affect regulated entities’ perception of WHD guidance and their interaction with agency materials. Stakeholders who rely on the interpretive rules proposed for removal (e.g., industry groups, compliance professionals, legal counsel) may need to adjust their internal citations and training materials to refer to the FOH rather than the CFR.

The Department does not anticipate any material disruption to regulated entities. WHD intends to provide clear cross-references in the FOH and to preserve the interpretive content in a familiar, searchable format. In many cases, stakeholders already rely on the FOH and other sub-regulatory guidance in practice.

4. Anticipated Benefits, Costs, and Transfers

i. Benefits

The proposed rule may yield several qualitative benefits. First, removing non-binding interpretive rules and policy statements from the CFR will reduce the risk that employers or courts perceive such guidance to be binding law. This could empower employers to dispute the application of such guidance in appropriate circumstances and reduce the likelihood of such guidance receiving unwarranted judicial deference in legal proceedings.

Second, the proposal would significantly reduce the size of the CFR administered by WHD, helping employers focus on provisions more likely to include binding legislative rules that they are required to follow. Specifically, removing parts 775, 776, 779, 782, 783, 784, 789, 793, and 794 from Subchapter B would remove approximately 229 pages from the 905 pages located in WHD’s assigned CFR Chapter 25—a 25 percent reduction. Reducing the volume of federal wage and hour regulations could improve employer compliance with wage and hour law and would be consistent with the deregulatory goals of Executive Order 14192.

Third, provisions in the parts proposed for removal have not been amended in decades and may be outdated or erroneous. For example, most of the provisions in part 779 have not been amended since 1970 and many include erroneous dollar thresholds

²³ See 58 FR 51735, 51741 (Oct. 4, 1993).

²⁴ 76 FR 3821.

²⁵ See 29 CFR chapter V (2024), <https://www.govinfo.gov/content/pkg/CFR-2024-title29-vol3/pdf/CFR-2024-title29-vol3-subtitleB-chapV.pdf>.

(such as multiple references to a \$1.60 per hour minimum wage) or address statutory provisions from the FLSA which have since been amended or repealed. Removing outdated guidance from the CFR will ensure that such errors do not confuse employers and employees about their rights and responsibilities. Relatedly, repurposing the content in these parts as sub-regulatory guidance will allow the Department to more expediently update such content than if it remains in the CFR.²⁶

If the Department determines that parts removed in this rulemaking should be reintroduced into the CFR, it would do so in future rulemakings inviting input from employers, employees, and other interested members of the public. This could improve the quality of such guidance by ensuring that the perspectives of outside parties have been taken into consideration in its development.

ii. Costs

This rule is deregulatory in nature and does not impose new requirements. Therefore, the Department does not anticipate any compliance costs. Potentially affected entities might experience negligible administrative costs in updating references to the removed CFR parts, but the Department expects these impacts to be de minimis.

iii. Transfers

The Department does not anticipate any transfer effects as a consequence of this rulemaking. This rulemaking does not affect any of the rights or responsibilities of employers, employees, and other interested parties.

5. Discussion of Regulatory Alternatives

The Department considered three alternatives to this proposal. First, the Department considered removing the entirety of Subchapter B so CFR provisions administered by WHD would consist entirely of legislative rules with the “force and effect of law.”²⁷ The Department rejected this approach because stakeholders in recent rulemakings have emphasized the utility of codifying interpretive guidance in the CFR, even if such guidance is non-binding. Therefore, the Department decided to propose

removing only those parts from Subchapter B which were not initially issued or subsequently amended in a notice-and-comment rulemaking.

Second, the Department considered removing all interpretive rules and policy statements within Subchapter B that were not issued or amended through notice-and-comment rulemaking. Under this approach, the Department would remove all of the parts it has proposed for removal in this NPRM as well as most of the provisions within part 778 (“Overtime Compensation”), part 780 (“Exemptions Applicable to Agriculture, Processing of Agricultural Commodities, and Related Subjects Under the Fair Labor Standards Act”), part 785 (“Hours Worked”), part 786 (“Miscellaneous Exemptions and Exclusions from Coverage”), and part 790 (“General Statement as to the Effect of the Portal-to-Portal Act of 1947 on the Fair Labor Standards Act of 1938”). The Department declined to take this approach in the NPRM because removing CFR sections from parts 778, 780, 785, 786, 788, and 790 could make those documents harder to understand (and therefore less useful) as standalone guidance documents. Additionally, the Department notes that, although specific sections in parts 778, 780, 785, 786, 788, and 790 may not have been addressed in notice-and-comment rulemakings, the public has had the opportunity to request changes to these sections in rulemakings which addressed other provisions in those parts.

Finally, the Department considered amending each part through separate notice-and-comment rulemakings, beginning with a rulemaking to address part 779 (the part in Subchapter B with the most outdated and erroneous content). This approach would be slower and more resource-intensive than the proposed approach, which could perpetuate many of the risks that are motivating this rulemaking as Subchapter B would continue to include entire parts which have not had the benefit of public comment.

6. Conclusion

The Department concludes that this rule, if finalized as proposed, will impose no regulatory burdens and may generate meaningful qualitative benefits. It supports WHD’s goals of transparency, procedural fairness, and public engagement, consistent with Executive Orders 12866, 13563, and 14192.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation

of an initial regulatory flexibility analysis (IRFA) and a final regulatory flexibility analysis (FRFA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. Because the changes proposed in this rulemaking are procedural in nature and would not affect the current rights and responsibilities of any small entity under the FLSA or any other federal wage and hour law, the Department certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities. The Department will transmit this certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act

The purpose of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*, includes minimizing the paperwork burden on affected entities. The PRA requires certain actions before an agency can adopt or revise a collection of information, including publishing for public comment a summary of the collection of information and a brief description of the need for and proposed use of the information.

This proposed rule does not contain a proposed collection of information or affect any existing information collection requests because the Department is merely proposing to relocate interpretive rules and policy statements from the CFR to sub-regulatory guidance, apart from obsolete provisions which have no practical impact. The Department welcomes comment on this determination.

D. Review Under Executive Order 13132

E.O. 13132, “Federalism,” 64 FR 43255 (August 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of

²⁶ At this time, the only content the Department proposes to omit from relocation into WHD’s FOH are provisions in Part 779 which are obviously obsolete or erroneous. However, the Department will continue reviewing the entirety of Subchapter B for outdated and erroneous content, including the other parts proposed for removal in this rulemaking.

²⁷ See Executive Order 12866 § 3(d), 58 FR 51737 (defining the term “regulation”).

regulatory policies that have federalism implications.

The Department has examined this proposed rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

E. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, “Civil Justice Reform,” imposes on Federal agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction.²⁸ Regarding the review required by section 3(a), section 3(b) of E.O. 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General.

Section 3(c) of E.O. 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. The Department has completed the required review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of E.O. 12988.

F. Review Under the Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of

\$100 million or more in any one year (adjusted annually for inflation), section 202 of the UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. 2 U.S.C. 1532(a), (b)). The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a “significant intergovernmental mandate,” and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them.

The Department examined this proposed rule according to the UMRA and its statement of policy and determined that the proposed rule does not contain a Federal intergovernmental mandate, nor is it expected to require expenditures of \$100 million or more in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector. As a result, the analytical requirements of the UMRA do not apply.

G. Review Under the Treasury and General Government Appropriations Act, 1999

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

H. Review Under Executive Order 12630

Pursuant to E.O. 12630, “Governmental Actions and Interference with Constitutionally Protected Property Rights,” 53 FR 8859 (March 18, 1988), the Department has determined that this proposed rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

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

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for Federal agencies to review most disseminations of information to the public under information quality

guidelines established by each agency pursuant to general guidelines issued by OMB. OMB’s guidelines were published at 67 FR 8452 (Feb. 22, 2002). The Department has reviewed this proposed rule under the OMB guidelines and has concluded that it is consistent with applicable policies in those guidelines.

J. Review Under Additional Executive Orders and Presidential Memoranda

The Department has examined this proposed rule and has determined that it is consistent with the policies and directives outlined in E.O. 14154, “Unleashing American Energy,” E.O. 14192, “Unleashing Prosperity Through Deregulation,” and Presidential Memorandum, “Delivering Emergency Price Relief for American Families and Defeating the Cost-of-Living Crisis.” This proposed rule is expected to be an Executive Order 14192 deregulatory action.

List of Subjects

29 CFR Part 775

Administrative practice and procedure, law enforcement, wages.

29 CFR Part 776

Construction industry, wages.

29 CFR Part 779

Reporting and recordkeeping requirements, wages.

29 CFR Part 782

Motor carriers, wages.

29 CFR Part 783

Seamen, wages.

29 CFR Part 784

Fisheries, seafood, wages.

29 CFR Part 789

Child labor, law enforcement, transportation, wages.

29 CFR Part 793

Radio, television, wages.

29 CFR Part 794

Petroleum, reporting and recordkeeping requirements, wages.

For the reasons set forth in the preamble, under the authority of 29 U.S.C. 201 *et seq.* the Department is proposing to amend chapter V, subchapter B of title 29 of the Code of Federal Regulations, as set forth below:

SUBCHAPTER B—OTHER REGULATIONS

- 1. Retitle subchapter B.

²⁸ 61 FR 4729 (Feb. 7, 1996).

PART 775—[REMOVED AND RESERVED]

- 2. Remove and reserve part 775, consisting of §§ 775.0 through 775.1.

PART 776—[REMOVED AND RESERVED]

- 3. Remove and reserve part 776, consisting of §§ 776.0 through 776.30.

PART 779—[REMOVED AND RESERVED]

- 4. Remove and reserve part 779, consisting of §§ 779.0 through 779.515.

PART 782—[REMOVED AND RESERVED]

- 5. Remove and reserve part 782, consisting of §§ 782.0 through 782.8.

PART 783—[REMOVED AND RESERVED]

- 6. Remove and reserve part 783, consisting of §§ 783.0 through 783.51.

PART 784—[REMOVED AND RESERVED]

- 7. Remove and reserve part 784, consisting of §§ 784.0 through 784.156.

PART 789—[REMOVED AND RESERVED]

- 8. Remove and reserve part 789, consisting of §§ 789.0 through 789.5.

PART 793—[REMOVED AND RESERVED]

- 9. Remove and reserve part 793, consisting of §§ 793.0 through 793.21.

PART 794—[REMOVED AND RESERVED]

- 10. Remove and reserve part 794, consisting of §§ 794.1 through 794.144.

Signed this 27th day of June, 2025.

Donald Harrison,
Acting Administrator, Wage and Hour Division.

[FR Doc. 2025–12314 Filed 6–30–25; 8:45 am]

BILLING CODE 4510–27–P

Notices

Federal Register

Vol. 90, No. 125

Wednesday, July 2, 2025

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 COMMERCE

Bureau of Industry and Security

Sensors and Instrumentation Technical Advisory Committee

AGENCY: Bureau of Industry and Security, U.S. Department of Commerce.

ACTION: Notice of Partially Closed Meeting.

SUMMARY: The Sensors and Instrumentation Technical Advisory Committee (SITAC) advises and assists the Secretary of Commerce and other Federal officials on matters related to export control policies; the SITAC will meet to review and discuss these matters. The meeting will be partially closed to the public pursuant to the exemptions under the Federal Advisory Committee Act (FACA) and the Government in the Sunshine Act.

DATES: The meeting will be held on July 29, 2025, from 12:30 p.m. to 3:00 p.m., Eastern Time (all times are Eastern Time). The open session will start at 12:30 p.m. and end at approximately 1:30 p.m. The closed session will start at approximately 1:30 p.m. and end no later than 3:00 p.m. Individuals requiring special accommodations to access the open session should contact TAC@bis.doc.gov no later than 11:59 p.m. on July 22, 2025, so that appropriate arrangements can be made. Individuals interested in participating virtually should contact TAC@bis.doc.gov no later than 11:59 p.m. on July 25, 2025.

ADDRESSES: The meeting will be held virtually. Both the open and closed sessions will be accessible via teleconference.

FOR FURTHER INFORMATION CONTACT: Kevin Coyne, Committee Liaison Officer, Bureau of Industry and Security, U.S. Department of Commerce. For additional information, contact

TAC@bis.doc.gov or by phone 202–482–4933.

SUPPLEMENTARY INFORMATION:

Background

The Sensors and Instrumentation Technical Advisory Committee (SITAC) advises and assists the Secretary of Commerce (Secretary) and other Federal officials and agencies with respect to actions designed to carry out the policy set forth in Section 1752 of the Export Control Reform Act. The purpose of the meeting is to have Committee members and U.S. Government representatives mutually review updated technical data and policy-driving information that has been gathered.

Agenda

The open session will include working group reports, open business discussions, and industry presentations. The closed session will include discussion of matters determined to be exempt from the open meeting and public participation requirements found in Sections 1009(a)(1) and 1009(a)(3) of the Federal Advisory Committee Act (FACA) (5 U.S.C. 1001–1014). The exemption is authorized by Section 1009(d) of the FACA, which permits the closure of advisory committee meetings, or portions thereof, if the head of the agency to which the advisory committee reports determines such meetings may be closed to the public in accordance with subsection (c) of the Government in the Sunshine Act (5 U.S.C. 552b(c)). In this case, the applicable provisions of 5 U.S.C. 552b(c) are subsection 552b(c)(4), which permits closure to protect trade secrets and commercial or financial information that is privileged or confidential, and subsection 552b(c)(9)(B), which permits closure to protect information that would be likely to disclose information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action. The closed session of the meeting will involve committee discussions and guidance regarding U.S. Government strategies and policies.

Open Session Attendance

The open session will be accessible via teleconference. Registration in advance is required to receive the meeting invite for virtual attendance. Individuals interested in participating

virtually should contact TAC@bis.doc.gov no later than 11:59 p.m. Eastern Time on July 25, 2025.

Special Accommodations

Individuals requiring special accommodations to access the public meeting should contact TAC@bis.doc.gov no later than 11:59 p.m. Eastern Time on Tuesday, July 22, 2025, so that appropriate arrangements can be made.

Public Participation

To the extent that time permits, members of the public may present oral statements to the SITAC. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of materials to the SITAC members, the SITAC suggests that members of the public forward their materials prior to the meeting via email to TAC@bis.doc.gov. Material submitted by the public will be made public and therefore should not contain confidential information. Meeting materials from the public session will be accessible via the Technical Advisory Committee (TAC) site at <https://tac.bis.doc.gov>, within 30 days after the meeting.

Closure Determination

The Acting Chief Financial Officer and Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined pursuant to 5 U.S.C. 1009(d)), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and the U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. 1009(a)(1) and 1009(a)(3). The remaining portions of the meeting will be open to the public.

Meeting cancellation

If the meeting is cancelled, a cancellation notice will be posted on the TAC website at <https://tac.bis.doc.gov>.

Kevin Coyne,

Committee Liaison Officer.

[FR Doc. 2025–12379 Filed 7–1–25; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration
[C–570–195]

Active Anode Material From the
People’s Republic of China: Amended
Preliminary Determination of
Countervailing Duty Investigation

AGENCY: Enforcement and Compliance,
International Trade Administration,
Department of Commerce.

SUMMARY: The U.S. Department of
Commerce (Commerce) is amending the
preliminary affirmative countervailing
duty (CVD) determination for active
anode material from the People’s
Republic of China (China) to correct
significant ministerial errors.

DATES: Applicable July 2, 2025.

FOR FURTHER INFORMATION CONTACT:
Benjamin Nathan or Gorden Struck, 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) 482–3834 or (202) 482–8151,
respectively.

SUPPLEMENTARY INFORMATION:

Background

In accordance with section 703(b) of
the Tariff Act of 1930, as amended (the
Act), and 19 CFR 351.205(b), on May 28,
2025, Commerce published its
preliminary affirmative determination
in the CVD investigation of active anode
material from China.¹ On May 28, 2025,
we received timely ministerial error
allegations from the American Active
Anode Material Producers (the
petitioner) alleging that Commerce
made a significant ministerial error in
the *Preliminary Determination* with
respect to the subsidy rates calculated
for Panasonic Global Procurement
(China) Co., Ltd. (GPC), and Panasonic
Corporation of China (PCN)
(collectively, Panasonic) and BTR New
Material Group Co., Ltd.² On June 2,
2025, Panasonic and BTR New Material
Group Sales Co., Ltd., BTR (Jiangsu)
New Energy Material Co., Ltd. and BTR
New Material Group Co., Ltd. (BTR)
submitted ministerial error rebuttal
comments.³

¹ See *Active Anode Material from the People’s
Republic of China: Preliminary Affirmative
Countervailing Duty Determination and Alignment
of Final Determination With Final Antidumping
Duty Determination*, 90 FR 22465 (May 28, 2025)
(*Preliminary Determination*), and accompanying
Preliminary Determination Memorandum (PDM).

² See Petitioner’s Letter, “Ministerial Error
Comments,” dated May 28, 2025.

³ See Panasonic’s Letter, “Rebuttal to Petitioner’s
Ministerial Error Allegations,” dated June 2, 2025;

Period of Investigation

The period of investigation (POI) is
January 1, 2023, through December 31,
2023.

Scope of the Investigation

The product covered by this
investigation is active anode material
from China. For a complete description
of the scope of this investigation, *see* the
Preliminary Determination.

**Analysis of Significant Ministerial
Error Allegations**

According to 19 CFR 351.224(e),
Commerce will analyze any comments
received and, if appropriate, correct any
significant ministerial error by
amending the preliminary
determination. A ministerial error is
defined in 19 CFR 351.224(f) as “an
error in addition, subtraction, or other
arithmetic function, clerical error
resulting from inaccurate copying,
duplication, or the like, and any other
similar type of unintentional error
which the Secretary considers
ministerial.”⁴ A significant ministerial
error is defined as a ministerial error,
the correction of which, singly or in
combination with other errors, would
result in: (1) a change of at least five
absolute percentage points in, but not
less than 25 percent of, the CVD rate
calculated in the original preliminary
determination; or (2) a difference
between a CVD rate of zero (or de
minimis) and a CVD rate greater than de
minimis, or vice versa.⁵

Methodology

In the *Preliminary Determination*,
Commerce made a significant
ministerial error within the meaning of
section 705(e) of the Act and 19 CFR
351.224(f) and (g)(1) in calculating the
countervailable subsidy rate for
Panasonic. Consistent with 19 CFR
351.224(e), Commerce is amending the
Preliminary Determination to reflect the
correction of this significant ministerial
error. Commerce also made other
ministerial errors, within the meaning of
19 CFR 351.224(f), in the calculation of
the countervailable subsidy rate for
Panasonic. These errors, in and of
themselves, are not significant within
the meaning of 19 CFR 351.224(g).
However, because correcting for these
errors in combination with the other
significant ministerial error alleged by
the petitioner satisfies the requirements
of 19 CFR 351.224(g)(1), we are also

see also BTR’s Letter, “Rebuttal to Petitioner’s
Preliminary Determination Ministerial Error
Comments,” dated June 2, 2025.

⁴ See section 705(e) of the Act.

⁵ See 19 CFR 351.224(g).

correcting for these errors by amending
the *Preliminary Determination*,
consistent with 19 CFR 351.224(e). In
correcting for these errors by amending
the *Preliminary Determination*,
consistent with 19 CFR 351.224(e), we
are revising the calculations for
Panasonic’s subsidy rate and the all-
others rate. For a complete discussion of
ministerial errors, *see* the Preliminary
Ministerial Error Memorandum.⁶

Amended Preliminary Determination

As a result of correcting the
ministerial errors described above, we
determine the following amended
preliminary net countervailable subsidy
rates for Panasonic and all other
producers/exporters:

Company	Subsidy rate (percent ad valorem)
Panasonic Global Procurement China Co., Ltd.; Panasonic Cor- poration of China ⁷	11.58
Shanghai Shaosheng Knitted Sweat Huzhou Kaijin New Energy Tech- nology Corp., Ltd.	* 721.03
All Others	* 721.03
	11.58

*Rate based on facts available with adverse
inferences.

Disclosure

Commerce intends to disclose its
calculations and analysis performed to
interested parties in this amended
preliminary determination within five
days of its 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.

**Amended Cash Deposits and
Suspension of Liquidation**

The collection of cash deposits and
suspension of liquidation will be
established according to the rates
calculated in this amended preliminary
determination. Because the amended
rates for Panasonic and all-others result
in increased cash deposits, they will be
effective on the date of the publication
of this notice in the **Federal Register**.
Parties will be notified of this

⁶ See Memorandum, “Analysis of Ministerial
Errors in the Preliminary Determination,” dated
concurrently with this notice (Preliminary
Ministerial Error Memorandum).

⁷ Panasonic is a trading company that sold subject
merchandise produced by an unaffiliated supplier
BTR New Material Group Co., Ltd., BTR (Jiangsu)
New Energy Material Co., Ltd., and BTR New
Material Group Sales Co., Ltd., (collectively, BTR)
and BTR’s affiliates. We are cumulating the benefits
received by BTR and BTR’s affiliates with the
benefits received by Panasonic into one rate for
Panasonic. For further explanation, *see Preliminary
Determination PDM* at 2–4 and 28–29.

determination, in accordance with section 703(d) and (f) of the Act.

U.S. International Trade Commission Notification

In accordance with section 703(f) of the Act, we will notify the ITC of our amended preliminary determination.

Notification to Interested Parties

This notice is issued and published pursuant to sections 703(f) and 777(i) of the Act, and 19 CFR 351.224(e).

Dated: June 27, 2025.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2025–12374 Filed 7–1–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–107]

Wooden Cabinets and Vanities and Components Thereof From the People's Republic of China: Notice of Court Decision Not in Harmony With the Final Determination of Countervailing Duty Investigation; Notice of Amended Final Determination; Notice of Amended Countervailing Duty Order, In Part

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On June 12, 2025, the U.S. Court of International Trade (CIT) issued its final judgment in *Dalian Meisen Woodworking Co., Ltd. v. United States*, Court no. 20–00110, sustaining the U.S. Department of Commerce (Commerce)'s third remand redetermination pertaining to the countervailing duty (CVD) investigation of wooden cabinets and vanities and components thereof (cabinets) from the People's Republic of China (China) covering the period of investigation (POI) January 1, 2018 through December 31, 2018. Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's final determination in that investigation, and that Commerce is amending the final determination and the resulting CVD order with respect to the countervailable subsidy rate assigned to The Ancientree Cabinet Co., Ltd. (Ancientree) and the all-others rate.

DATES: Applicable June 22, 2025.

FOR FURTHER INFORMATION CONTACT: Kelsie Hohenberger, 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) 482–2517.

SUPPLEMENTARY INFORMATION:

Background

On February 28, 2020, Commerce published its *Final Determination* in the CVD investigation of cabinets from China.¹ Commerce found that countervailable subsidies were being provided to producers and/or exporters of cabinets from China.² Commerce subsequently published the CVD order on cabinets from China.³

Ancientree, Dalian Meisen Woodworking Co., Ltd. (Meisen), and a U.S. importer (Cabinets to Go, LLC), appealed Commerce's *Final Determination*. On May 12, 2022, the CIT remanded the *Final Determination* to Commerce with respect to Commerce's application of facts otherwise available with an adverse inference (AFA) to the two mandatory respondents, Ancientree and Meisen, for the Export Buyer's Credit Program (EBCP) and directed Commerce to find a practical solution to verify the companies' claimed non-use of the program.⁴

In its first remand redetermination, issued in August 2022, Commerce reopened the record to obtain information from Ancientree and Meisen and their U.S. customers concerning outstanding lending during the POI.⁵ Meisen did not provide the information; Ancientree provided the information for some, but not all, of its customers. Accordingly, Commerce continued to apply AFA to both companies for the EBCP. The CIT remanded for a second time, sustaining Commerce's application of AFA to Meisen, but again remanding the decision as it related to Ancientree.⁶

¹ See *Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Final Affirmative Countervailing Duty Determination*, 85 FR 11962 (February 28, 2020) (*Final Determination*).

² *Id.*

³ See *Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Countervailing Duty Order*, 85 FR 22134 (April 21, 2020) (*Order*).

⁴ See *Dalian Meisen Woodworking Co., Ltd. v. United States*, Court No. 20–00110, Slip Op. 22–45 (CIT May 12, 2022).

⁵ See *Final Results of Redetermination Pursuant to Court Remand, Dalian Meisen Woodworking Co., Ltd. v. United States*, Court No. 20–00110, Slip Op. 22–45 (CIT May 12, 2022), dated August 5, 2022, available at <https://access.trade.gov/resources/remands/22-45.pdf>.

⁶ See *Dalian Meisen Woodworking Co., Ltd. v. United States*, Court No. 20–00110, Slip Op. 23–57 (CIT Apr. 20, 2023).

Regarding Ancientree, the CIT found that Commerce must attempt to verify Ancientree's submissions and either pro rate Ancientree's subsidy rate or conclude that the company did not use the EBCP at all, and then must also recalculate Ancientree's rate and the all-others rate accordingly.

In its second remand redetermination, issued in December 2023, Commerce determined that, because a significant percentage of Ancientree's customers declined (or otherwise were unable) to provide verifiable information concerning POI lending, we were unable to successfully verify the information regarding non-use; accordingly, we continued to apply AFA for the EBCP.⁷ The CIT remanded for a third time, stating that, because Commerce was able to successfully verify a portion of the information, Commerce was required to (1) recalculate Ancientree's total subsidy rate to reflect a revised/pro-rated EBCP determination; (2) determine a customer-specific subsidy rate that excludes a program rate for the EBCP for each Ancientree customer whose non-use of the EBCP was successfully verified; and (3) recalculate the all-others rate accordingly.⁸

In its final remand redetermination, issued in November 2024, in compliance with the CIT's order, Commerce (1) recalculated Ancientree's subsidy rate to reflect a pro-rated benefit for Ancientree, (2) calculated customer-specific assessment rates, and (3) revised the all-others rate to reflect the change to Ancientree's cash deposit rate.⁹ The CIT sustained Commerce's final redetermination.¹⁰

Timken Notice

In its decision in *Timken*,¹¹ as clarified by *Diamond Sawblades*,¹² the U.S. Court of Appeals for the Federal Circuit held that, pursuant to sections 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must

⁷ See *Final Results of Redetermination Pursuant to Court Remand, Dalian Meisen Woodworking Co., Ltd. v. United States*, Court No. 20–00110, Slip Op. 23–57 (CIT April 20, 2023), dated December 6, 2023, available at <https://access.trade.gov/Resources/remands/23-57.pdf>.

⁸ See *Dalian Meisen Woodworking Co., Ltd. v. United States*, Court No. 20–00110, Slip Op. 24–83 (CIT July 22, 2024).

⁹ See *Final Results of Redetermination Pursuant to Court Remand, Dalian Meisen Woodworking Co., Ltd. v. United States*, Court No. 20–00110, Slip Op. 24–83 (CIT July 22, 2024), dated November 12, 2024.

¹⁰ See *Dalian Meisen Woodworking Co., Ltd. v. United States*, Court No. 20–00110, Slip Op. 25–74 (CIT June 12, 2025).

¹¹ See *Timken Co. v. United States*, 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

¹² See *Diamond Sawblades Manufacturers Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

publish a notice of court decision that is not “in harmony” with a Commerce determination and must suspend liquidation of entries pending a “conclusive” court decision. The CIT’s June 12, 2025, judgment constitutes a final decision of the CIT that is not in harmony with Commerce’s *Final Determination*. Thus, this notice is published in fulfillment of the publication requirements of *Timken*.

Amended Final Determination and CVD Order

Because there is now a final court judgment, Commerce is amending its *Final Determination and Order* with respect to Ancientree and all other companies as follows:

Company	Subsidy rate (percent)
The Ancientree Cabinet Co., Ltd. ¹³	5.06
All Others	18.17

Cash Deposit Requirements

Because Ancientree has a superseding cash deposit rate, *i.e.*, there have been final results published in a subsequent administrative review, this notice will not affect the current cash deposit rate for Ancientree. For the all-others rate, Commerce will issue revised cash deposit instructions to U.S. Customs and Border Protection.

Liquidation of Suspended Entries

At this time, Commerce remains enjoined by CIT order from liquidating entries of subject merchandise that were exported by Ancientree, and that were entered, or withdrawn from warehouse, for consumption, during the period August 12, 2019, through December 31, 2022, excluding the period from December 10, 2019, to April 16, 2020.

Next, Commerce remains enjoined from liquidating entries produced and/or exported by Meisen which were entered, or withdrawn from warehouse, for consumption, during the period August 12, 2019, through December 31, 2020, excluding the period from December 10, 2019, to April 16, 2020.

Commerce also remains enjoined from liquidating entries produced and/or exported by Qingdao Haiyan Drouot Household Co., Ltd., Xuzhou Yihe Wood Co., Ltd., Kunshan Baiyulan Furniture Co., Ltd., or Jiangsu Beichen Wood Co., Ltd., and imported by Cabinets to Go, LLC which were

entered, or withdrawn from warehouse, for consumption, during the period August 12, 2019, through December 31, 2020, excluding the period from December 10, 2019, to April 16, 2020.¹⁴

These entries will remain enjoined pursuant to the terms of the injunctions during the pendency of any appeals process.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) and 777(i)(1) of the Act.

Dated: June 27, 2025.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2025–12373 Filed 7–1–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–929]

Small Diameter Graphite Electrodes From the People’s Republic of China: Final Results of the Expedited Third Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on small diameter graphite electrodes (electrodes) from the People’s Republic of China (China) would be likely to lead to the continuation or recurrence of dumping at the levels indicated in the “Final Results of Sunset Review” section of this notice.

DATES: Applicable July 2, 2025.

FOR FURTHER INFORMATION CONTACT: Luke Engan, Trade Agreements Policy and Negotiations, Enforcement and Compliance, International Trade

Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1745.

SUPPLEMENTARY INFORMATION:

Background

On February 26, 2009, Commerce published the AD order on electrodes from China in the **Federal Register**.¹ On March 3, 2025, Commerce published the notice of initiation of the third sunset review of the *Order*, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).²

On March 18, 2025, Commerce received a timely and complete notice of intent to participate in the sunset review from Tokai Carbon GE LLC and GrafTech International Ltd. (collectively, the domestic interested parties) within the deadline specified in the 19 CFR 351.218(d)(1)(i).³ The domestic interested parties claimed interested party status within the meaning of section 771(9)(C) of the Act as manufacturers, producers, or wholesalers in the United States of a domestic like product.⁴ On March 20, 2025, Commerce notified the U.S. International Trade Commission (ITC) that it had received a notice of intent to participate from the domestic interested parties.⁵

On April 2, 2025, pursuant to 19 CFR 351.218(d)(3)(i), domestic interested parties filed a timely and adequate substantive response.⁶ Commerce did not receive a substantive response from any respondent interested party. On April 22, 2025, Commerce notified the ITC that it did not receive substantive response from any respondent interested parties.⁷ As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce is conducting an expedited (120-day) sunset review of the *Order*.

¹ See *Antidumping Duty Order: Small Diameter Graphite Electrodes from the People’s Republic of China*, 74 FR 8775 (February 26, 2009) (*Order*).

² See *Initiation of Five-Year (Sunset) Reviews*, 90 FR 11039 (March 3, 2025).

³ See Domestic Interested Parties’ Letter, “Small Diameter Graphite Electrodes from the People’s Republic of China—Five-Year (3rd Sunset) Review of Antidumping Duty Order—Notice of Intent to Participate,” dated March 18, 2025.

⁴ *Id.* at 2.

⁵ See Commerce’s Letter, “Sunset Reviews Initiated on March 3, 2025,” dated March 20, 2025.

⁶ See Domestic Interested Parties’ Letter, “Small Diameter Graphite Electrodes from the People’s Republic of China—Five-Year (3rd Sunset) Review of Antidumping Duty Order—Domestic Industry’s Substantive Response,” dated April 2, 2025.

⁷ See Commerce’s Letter, “Sunset Reviews Initiated on March 3, 2025,” dated April 22, 2025.

¹³ In the investigation, Commerce found the following companies to be cross-owned with Ancientree: Jiangsu Hongjia Wood Co., Ltd., Shanghai Branch, and Shanghai Hongjia Wood Co., Ltd.

¹⁴ Although Cabinets to Go, LLC’s injunction also covered entries from Senke Manufacturing Company (Senke), Senke was a participant in the 2019–2020 administrative review and received a subsidy rate. See *Wooden Cabinets and Vanities and Components Thereof from the People’s Republic of China: Final Results and Partial Rescission of Countervailing Duty Administrative Review; 2019–2020*, 87 FR 51967 (August 24, 2022). Accordingly, the future disposition of entries of merchandise produced and/or exported by Senke, and entered during the 2019–2020 review period, is not covered by Commerce’s remand redetermination, and the applicable rate for entries from this company that were imported by Cabinets to Go, LLC is based on the outcome of the 2019–2020 review.

Scope of the Order

The merchandise covered by this *Order* is electrodes from China. For the full description of the scope of the *Order*, see the Issues and Decisions Memorandum.⁸

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of dumping in the event of revocation of the *Order* and the magnitude of the margins likely to prevail if the *Order* were to be revoked, is provided in the Issues and Decision Memorandum.⁹ A list of the topics discussed in the Issues and Decision Memorandum is attached 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 directly accessed at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Final Results of Sunset Reviews

Pursuant to sections 751(c)(1), and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to the continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average dumping margins up to 159.64 percent.

Notification Regarding 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. Timely notification of the return or destruction of APO materials, or conversion to judicial protective, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

⁸ See Memorandum, "Issues and Decision Memorandum for the Final Results of the Expedited Third Sunset Review of the Antidumping Duty Order on Small Diameter Graphite Electrodes from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice.

⁹ *Id.*

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218 and 19 CFR 351.221(c)(5)(ii).

Dated: June 27, 2025.

Christopher Abbott,

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. History of the *Order*
- V. Legal Framework
- VI. Discussion of the Issues
 1. Likelihood of Continuation or Recurrence of Dumping
 2. Magnitude of the Margins of Dumping Likely to Prevail
- VII. Final Results of Sunset Review
- VIII. Recommendation

[FR Doc. 2025–12372 Filed 7–1–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–107]

Wooden Cabinets and Vanities and Components Thereof From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on wooden cabinets and vanities and components thereof (wooden cabinets) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies, at the levels indicated in the "Final Results of Sunset Review" section of this notice.

DATES: Applicable July 2, 2025.

FOR FURTHER INFORMATION CONTACT: Matthew Shea, Trade Agreements Policy and Negotiations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202–482–2583.

SUPPLEMENTARY INFORMATION:

Background

On March 3, 2025, Commerce published the notice of initiation of the five-year review of the *Order*,¹ pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).² On March 18, 2025, Commerce received a notice of intent to participate in this review from the American Kitchen Cabinet Alliance (AKCA) and MasterBrand Cabinets, LLC (MasterBrand) (collectively, the petitioner), within the deadline specified in 19 CFR 351.218(d)(1)(i).³ The petitioners claimed interested party status under section 771(9)(C) and (E) of the Act, as manufacturers of a domestic like product in the United States. On April 2, 2025, the petitioners provided complete substantive responses for this review within the 30-day deadline specified in 19 CFR 351.218(d)(3)(ii).⁴ Commerce did not receive a substantive response from any respondent interested party, nor was a hearing requested.

On April 22, 2025, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from the Government of China (GOC) respondent interested parties.⁵ As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the order.

Scope of the Order

The product covered by the *Order* is wooden cabinets from China. For the full description of the scope of the *Order*, see the Issues and Decisions Memorandum.⁶

¹ See *Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Notice of Countervailing Duty Order*, 74 FR 22134 (April 21, 2020) (*Order*).

² See *Initiation of Five-Year (Sunset) Reviews*, 90 FR 11039 (March 3, 2025).

³ See AKCA's Letter, "Notice of Intent to Participate in the First Five-Year Review," dated March 18, 2025; see also MasterBrand's Letter, "Notice of Intent to Participate in Sunset Review," dated March 18, 2025.

⁴ See AKCA's Letter, "Domestic Interested Party's Substantive Response to the Notice of Initiation," dated April 2, 2025 (AKCA's Substantive Response); see also MasterBrand's Letter, "Substantive Response to Notice of Initiation of Sunset Review," April 2, 2025 (MasterBrand's Substantive Response).

⁵ See Commerce's Letter, "Sunset Reviews Initiated on March 3, 2025," dated April 22, 2025.

⁶ See Memorandum, "Issues and Decision Memo for the Final Results of the Expedited Sunset Review of the Countervailing Duty Order on Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of subsidization in the event of revocation of the *Order* and the countervailable subsidy rates likely to prevail if the *Order* were to be revoked, is provided in the Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision

Memorandum is attached 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 directly accessed

at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Final Results of Sunset Reviews

Pursuant to sections 751(c)(1), 752(b) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies at the following net countervailable subsidy rates:

Producers/exporter	Subsidy rate (percent <i>ad valorem</i>)
The Ancientree Cabinet Co., Ltd	13.33
Dalian Meisen Woodworking Co., Ltd	18.27
Rizhao Foremost Woodwork Manufacturing Company	31.18
Henan AiDiJia Furniture Co., Ltd	293.45
Deway International Trade Co., Ltd	293.45
All Others	20.93

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to APO of the responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218 and 19 CFR 351.221(c)(5)(ii).

Dated: June 27, 2025.

Christopher Abbott,

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. History of the *Order*
- V. Legal Framework
- VI. Discussion of the Issues
 1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
 2. Net Countervailable Subsidy Rates Likely to Prevail
 3. Nature of the Subsidies
- VII. Final Results of Sunset Review
- VIII. Recommendation

[FR Doc. 2025-12371 Filed 7-1-25; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings**

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR25-60-000.
Applicants: Columbia Gas of Virginia Inc.

Description: § 284.123 Rate Filing: Application for Approval of Revised Statement of Operating Conditions 6-2025 to be effective 5/30/2025.

Filed Date: 6/26/25.

Accession Number: 20250626-5021.

Comment Date: 5 p.m. ET 7/17/25.

Docket Numbers: RP25-972-000.

Applicants: Portland Natural Gas Transmission System.

Description: § 4(d) Rate Filing: PNGTS Open Season Updates to be effective 7/26/2025.

Filed Date: 6/26/25.

Accession Number: 20250626-5147.

Comment Date: 5 p.m. ET 7/8/25.

Docket Numbers: RP25-973-000.

Applicants: Wyoming Interstate Company, L.L.C.

Description: § 4(d) Rate Filing: Non-Conforming Negotiated Rate Agreements Filing—Citadel to be effective 7/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627-5058.

Comment Date: 5 p.m. ET 7/9/25.

Docket Numbers: RP25-974-000.

Applicants: Big Sandy Pipeline, LLC.

Description: § 4(d) Rate Filing: Big Sandy EPC 2025 to be effective 8/1/2025.

Filed Date: 6/27/25.

Accession Number: 20250627-5059.

Comment Date: 5 p.m. ET 7/9/25.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP22-1001-000.

Applicants: Eastern Gas Transmission and Storage, Inc.

Description: Report Filing: EGTS—Operational Gas Sales Report—2025 to be effective N/A.

Filed Date: 6/27/25.

Accession Number: 20250627-5037.

Comment Date: 5 p.m. ET 7/9/25.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

The Commission's Office of Public Participation (OPP) supports meaningful

public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organization, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: June 27, 2025.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2025-12338 Filed 7-1-25; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG25-361-000.

Applicants: Clean Energy Future—Trumbull, LLC.

Description: Clean Energy Future—Trumbull, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/26/25.

Accession Number: 20250626-5175.

Comment Date: 5 p.m. ET 7/17/25.

Docket Numbers: EG25-362-000.

Applicants: Kelso Solar LLC.

Description: Kelso Solar LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/27/25.

Accession Number: 20250627-5086.

Comment Date: 5 p.m. ET 7/18/25.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL25-95-000.

Applicants: Michigan Public Power Agency v. Michigan Electric Transmission Company, LLC.

Description: Complaint of Michigan Public Power Agency v. Michigan Electric Transmission Company, LLC.

Filed Date: 6/25/25.

Accession Number: 20250625-5186.

Comment Date: 5 p.m. ET 7/15/25.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10-1818-040.

Applicants: Public Service Company of Colorado.

Description: Triennial Market Power Analysis for Southwest Region of Public Service Company of Colorado.

Filed Date: 6/26/25.

Accession Number: 20250626-5168.

Comment Date: 5 p.m. ET 8/25/25.

Docket Numbers: ER25-2645-000.

Applicants: Sun Streams Expansion, LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/27/2025.

Filed Date: 6/26/25.

Accession Number: 20250626-5134.

Comment Date: 5 p.m. ET 7/17/25.

Docket Numbers: ER25-2646-000.

Applicants: Wildcat Ranch Energy Storage, LLC.

Description: § 205(d) Rate Filing: Application for Market-Based Rate Authorization—Wildcat Ranch Energy Storage to be effective 8/26/2025.

Filed Date: 6/26/25.

Accession Number: 20250626-5136.

Comment Date: 5 p.m. ET 7/17/25.

Docket Numbers: ER25-2647-000.

Applicants: Three Corners Prime Tenant, LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/27/2025.

Filed Date: 6/26/25.

Accession Number: 20250626-5139.

Comment Date: 5 p.m. ET 7/17/25.

Docket Numbers: ER25-2648-000.

Applicants: Umbriel Solar, LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/27/2025.

Filed Date: 6/26/25.

Accession Number: 20250626-5142.

Comment Date: 5 p.m. ET 7/17/25.

Docket Numbers: ER25-2649-000.

Applicants: Tilden Solar, LLC.

Description: § 205(d) Rate Filing: Tilden Solar Market-Based Rate to be effective 8/27/2025.

Filed Date: 6/26/25.

Accession Number: 20250626-5151.

Comment Date: 5 p.m. ET 7/17/25.

Docket Numbers: ER25-2650-000.

Applicants: Puget Sound Energy, Inc.

Description: § 205(d) Rate Filing: Beaver Creek Wind OA between PSE and NorthWestern, RS-9003 to be effective 7/1/2025.

Filed Date: 6/26/25.

Accession Number: 20250626-5159

Comment Date: 5 p.m. ET 7/17/25.

Docket Numbers: ER25-2651-000.

Applicants: Wilmot Energy Center II, LLC, Wildcat Ranch Wind Project, LLC.

Description: § 205(d) Rate Filing: Wildcat Ranch Wind Project, LLC submits tariff filing per 35.12: Application for Market-Based Rate Authorization—Wilmot Energy Center II to be effective 8/26/2025.

Filed Date: 6/26/25.

Accession Number: 20250626-5167.

Comment Date: 5 p.m. ET 7/17/25.

Docket Numbers: ER25-2652-000.

Applicants: Public Service Company of New Mexico.

Description: § 205(d) Rate Filing: Revisions to LGIP—COD to be effective 6/27/2025.

Filed Date: 6/26/25.

Accession Number: 20250626-5172.

Comment Date: 5 p.m. ET 7/17/25.

Docket Numbers: ER25-2653-000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Proposed Cost Allocation to Implement DOE Order 202-25-4 Pursuant to FPA 202(c) to be effective 6/1/2025.

Filed Date: 6/26/25.

Accession Number: 20250626-5181.

Comment Date: 5 p.m. ET 7/7/25.

Docket Numbers: ER25-2654-000.

Applicants: ISO New England Inc., New England Power Pool Participants Committee, Cross-Sound Cable Company, LLC.

Description: Compliance filing: ISO New England Inc. submits tariff filing per 35: ISO-NE, NEPOOL & Cross Sound Cable; Revisions to Schedules 18 and 24 to be effective 2/27/2026.

Filed Date: 6/27/25.

Accession Number: 20250627-5032.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25-2655-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2881R21 City of Chanute, KS NITSA NOA to be effective 9/1/2025.

Filed Date: 6/27/25.

Accession Number: 20250627-5039.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25-2656-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1518R29 Arkansas Electric Cooperative Corp NITSA NOA to be effective 9/1/2025.

Accession Number: 20250627-5055.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25-2657-000.

Applicants: ISO New England Inc., Eversource Energy Service Company (as agent).

Description: Compliance filing: Eversource Energy Service Company (as agent) submits tariff filing per 35: PTO AC; Revisions to Schedules 20A and 21 in Compliance with Order No. 676 to be effective 2/27/2026.

Filed Date: 6/27/25.

Accession Number: 20250627-5060.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25-2658-000.

Applicants: New Covert Generating Company, LLC.

Description: Tariff Amendment: Notice of Cancellation of Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5067.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2659–000.

Applicants: Parkway Generation Essex, LLC.

Description: Tariff Amendment: Notice of Cancellation of Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5071.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2660–000.

Applicants: Aron Energy Prepay 34 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5081.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2661–000.

Applicants: Aron Energy Prepay 35 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5082.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2662–000.

Applicants: Aron Energy Prepay 41 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5083.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2663–000.

Applicants: Aron Energy Prepay 42 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5084.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2664–000.

Applicants: Aron Energy Prepay 44 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5087.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2665–000.

Applicants: Aron Energy Prepay 45 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5088.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2666–000.

Applicants: Aron Energy Prepay 46 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5090.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2667–000.

Applicants: Aron Energy Prepay 47 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5091.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2668–000.

Applicants: Aron Energy Prepay 43 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5092.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2669–000.

Applicants: Aron Energy Prepay 51 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5093.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2670–000.

Applicants: Aron Energy Prepay 52 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5094.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2671–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: Compliance filing: Order No. 676–K Compliance Filing to be effective 2/27/2026.

Filed Date: 6/27/25.

Accession Number: 20250627–5096.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2672–000.

Applicants: Aron Energy Prepay 53 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5097.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2673–000.

Applicants: Aron Energy Prepay 54 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5098.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2674–000.

Applicants: Aron Energy Prepay 57 LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5099.

Comment Date: 5 p.m. ET 7/18/25.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organizations, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Dated: June 27, 2025.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2025–12333 Filed 7–1–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings #2**

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG25–363–000.

Applicants: 64NB 8me LLC.

Description: 64NB 8me LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/27/25.

Accession Number: 20250627–5170.

Comment Date: 5 p.m. ET 7/18/25.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER25–2675–000.

Applicants: West Boylston Energy Storage I LLC.

Description: Initial Rate Filing:

Baseline new to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5101.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2676–000.

Applicants: OSCII Gildersleeve, LLC.

Description: Initial Rate Filing:

Baseline new to be effective 6/28/2025

Filed Date: 6/27/25.

Accession Number: 20250627–5102.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2677–000.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: § 205(d) Rate Filing:

2025–06–27 Tariff Consolidation for Schedules 7,8,9 to be effective 10/1/2019.

Filed Date: 6/27/25.

Accession Number: 20250627–5104.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2678–000.

Applicants: Southwest Power Pool,

Inc.

Description: § 205(d) Rate Filing:

2415R23 Kansas Municipal Energy Agency NITSA and NOA to be effective 9/1/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5107.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2679–000.

Applicants: Heritage Power

Marketing, LLC.

Description: § 205(d) Rate Filing:

Market-Based Rate Tariff Revisions to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5108.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2680–000.

Applicants: New York Independent

System Operator, Inc.

Description: Compliance filing: NYISO Compliance Filing re: Order 676–K NAESB/WEQ Standards to be effective 2/27/2026.

Filed Date: 6/27/25.

Accession Number: 20250627–5112.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2681–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1276R38 Evergy Metro NITSA NOA to be effective 9/1/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5113.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2682–000.

Applicants: FL Solar 8, LLC.

Description: § 205(d) Rate Filing: FL Solar 8 Initial MBR Tariff Filing to be effective 8/1/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5114.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2683–000.

Applicants: Richland Township Solar II, LLC.

Description: § 205(d) Rate Filing: Shared Facilities Agreement to be effective 6/28/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5117.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2684–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii): Stellar (Shamrock Solar) LGIA Filing to be effective 6/13/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5127.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2685–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii): AMEA NITSA Amendment Termination Filing to be effective 5/30/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5130.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2686–000.

Applicants: Appalachian Power Company.

Description: § 205(d) Rate Filing: Application to Recover Deferred Fuel Expenses in Market-Based Rate Contracts to be effective 8/27/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5141.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2687–000.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance filing: Order No. 676–K Compliance Revisions to Tariff, Section 4.2 to be effective 2/27/2026.

Filed Date: 6/27/25.

Accession Number: 20250627–5162.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2688–000.

Applicants: Star Light Energy Center, LLC.

Description: § 205(d) Rate Filing: Application for Market-Based Rate Authorization—Star Light Energy Ctr to be effective 8/27/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5195.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2689–000.

Applicants: Duke Energy Progress, LLC.

Description: § 205(d) Rate Filing: DEP–DEP Engineering and Procurement Agreement RS No. 471 to be effective 8/27/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5196.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2690–000.

Applicants: Key Energy Storage, LLC.

Description: § 205(d) Rate Filing: Application for Market-Based Rate Authorization—Key Energy Storage to be effective 8/27/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5197.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2691–000.

Applicants: Panhandle Solar, LLC.

Description: § 205(d) Rate Filing: Application for Market-Based Rate Authorization—Panhandle Solar to be effective 8/27/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5198.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2692–000.

Applicants: DTE Electric Company.

Description: § 205(d) Rate Filing: Amendment to Rate Agreement 28—to be effective 8/1/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5199.

Comment Date: 5 p.m. ET 7/18/25.

Docket Numbers: ER25–2693–000.

Applicants: Duke Energy Progress, LLC.

Description: Tariff Amendment: DEP–DEP Notice of Termination of SA 456 to be effective 8/27/2025.

Filed Date: 6/27/25.

Accession Number: 20250627–5201.

Comment Date: 5 p.m. ET 7/18/25.

The filings are accessible in the Commission's eLibrary system (<https://>

elibrary.ferc.gov/idmws/search/fercgensearch.asp by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

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Dated: June 27, 2025.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2025-12336 Filed 7-1-25; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP25-204-000]

Northwest Pipeline LLC; Notice of Schedule for the Preparation of an Environmental Assessment for the Kemmerer Horsepower Replacement Project

On April 10, 2025, Northwest Pipeline LLC (Northwest) filed an application in Docket No. CP25-204-000 requesting a Certificate of Public Convenience and Necessity pursuant to Section 7(c) and Authorization pursuant to Section 7(b) of the Natural Gas Act to construct, operate, and abandon certain natural gas pipeline facilities. The proposed project is known as the Kemmerer Horsepower Replacement Project (Project), and would retire four legacy reciprocating engine compressors

and one legacy gas turbine and replace these facilities with one natural gas-fired turbine-driven compressor in Lincoln County, Wyoming. According to Northwest, the Project would improve system reliability due to the high maintenance needs and costs associated with the older units, as well as conform with Northwest's Modernization and Emissions Reduction Program.

On April 16, 2025, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's environmental document for the Project.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the Project and the planned schedule for the completion of the environmental review.¹

Schedule for Environmental Review

Issuance of EA—October 9, 2025

90-day Federal Authorization Decision

Deadline²—January 7, 2026

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

Northwest proposes to construct and operate, on land owned and managed by the U.S. Bureau of Land Management (BLM): one Solar Mars 90 gas-fired turbine having approximately 13,220 ISO-rated horsepower; a compressor building to house the turbine and associated compressor package; power and unit control buildings; office and warehouse space; and other ancillary facilities to the east of its existing Kemmerer Compressor Station within an approximately 80-acre parcel in Lincoln County, Wyoming. Upon the new compressor station's completion, Northwest would abandon and remove

the existing station facilities in accordance with the terms and conditions of the BLM right-of-way grant and requirements set forth in Title 43 Code of Federal Regulations Sections 2800 and 2880.

Background

On June 11, 2025, the Commission issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Kemmerer Horsepower Replacement Project* (Notice of Scoping). The Notice of Scoping was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. As of the date of issuance of this Notice of Schedule, we have received no comments in response to the Notice of Scoping. Any substantive comments received will be addressed in the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organizations, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208-FERC or on the FERC website (www.ferc.gov). Using the "eLibrary" link, select "General Search" from the eLibrary menu, enter the selected date range and "Docket Number" excluding the last three digits (*i.e.*, CP25-204), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208-3676, TTY (202) 502-8659, or at FERCOnlineSupport@ferc.gov. The eLibrary link on the FERC website also provides access to the texts of formal

¹ For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX-019-20-000-1750866092.

² The Commission's deadline applies to the decisions of other federal agencies, and state agencies acting under federally delegated authority, that are responsible for federal authorizations, permits, and other approvals necessary for proposed projects under the Natural Gas Act. Per 18 CFR 157.22(a), the Commission's deadline for other agency's decisions applies unless a schedule is otherwise established by federal law.

documents issued by the Commission, such as orders, notices, and rule makings.

Dated: June 27, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–12334 Filed 7–1–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15404–000]

Claiborne Hydroelectric, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On May 30, 2025, Claiborne Hydroelectric, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of hydropower project to be located at the U.S. Army Corps of Engineers' (Corps) Claiborne Lock and Dam, on Alabama River, near City of Franklin, Monroe County, Alabama. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed Claiborne lock and dam Hydroelectric Project would consist of the following: (1) a 98-foot-wide, 50-foot-long armored intake structure; (2) a 98-foot-wide, 187-foot-long reinforced concrete powerhouse, located downstream of the western abutment of the Corps' dam, hosting two identical 9.95 MW turbine generators;

(3) a 100-foot-long, 98-foot-wide armored tailrace that would direct flow to the river downstream of the dam; and (4) a 4.5 mile-long, 230 kilovolt transmission line. The proposed project would have an estimated annual generation of 139.5 gigawatt-hours.

Applicant Contact: Jeremy King, Current Hydro, One Boston Place, Suite 2600, Boston, MA; phone: (706) 835 8516.

FERC Contact: Prabharanjani Madduri; phone: (202) 502–8017, or by email at prabharanjani.madduri@ferc.gov. Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing

applications: 60 days from the issuance of this notice, on or before 5:00 p.m. Eastern Time on August 25, 2025. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at <https://ferconline.ferc.gov/eFiling.aspx>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/QuickComment.aspx>. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–15404.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, community organizations, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

More information about this project, including a copy of the application, can be viewed, or printed on the "eLibrary" link of the Commission's website at: <https://elibrary.ferc.gov/eLibrary/search>. Enter the docket number (P–15404) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: June 27, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–12337 Filed 7–1–25; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2024–0093; FRL–12575–01–OCSPP]

Cancellation Order for Certain Pesticide Registrations and/or Amendments To Terminate Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations and/or amendments to terminate uses, voluntarily requested by the registrants and accepted by the Agency, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows a December 17, 2024, **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 3 of Unit II to voluntarily cancel and/or amend to terminate uses of all these product registrations. In the December 17, 2024, notice, EPA indicated that it would issue an order implementing the cancellations and/or amendments to terminate uses, unless the Agency received substantive comments within the 30-day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency received one anonymous comment on the notice, but it did not merit its further review of the requests. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations and/or amendments to terminate uses. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations and/or amendments are effective July 2, 2025.

FOR FURTHER INFORMATION CONTACT: Christopher Green, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–2707; email address: green.christopher@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical

industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How Can I Get Copies of this Document and Other Related Information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2024-0093, is available

at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (202) 566-1744. Please review

the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

II. What Action is the Agency Taking?

This notice announces the cancellations and/or amendments to terminate uses, as requested by registrants, of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Tables 1 and 2 of this unit.

TABLE 1—PRODUCT CANCELLATIONS

Registration No.	Company No.	Product name	Active ingredients
279-3455	279	Marvel Herbicide	Fluthiacet-methyl (108803/117337-19-6)—(1.2%), Fomesafen (123803/72178-02-0)—(30.08%).
279-3568	279	Dawn Herbicide	Sodium salt of fomesafen (123802/108731-70-0)—(22.8%).
279-3569	279	Rhythm Herbicide	Sodium salt of fomesafen (123802/108731-70-0)—(22.1%).
2749-642	2749	Dicropophos Technical	Dicropophos (035201/141-66-2)—(85%).
2749-643	2749	Dicromax XP Insecticide	Bifenthrin (128825/82657-04-3)—(10.8%), Dicropophos (035201/141-66-2)—(43.1%).
7401-38	7401	Ferti-Lome Liquid Carbaryl Home Garden Spray	Carbaryl (056801/63-25-2)—(23.7%).
7401-69	7401	Ferti Lome Garden Dust	Carbaryl (056801/63-25-2)—(5%).
7401-166	7401	Hi-Yield 10% Carbaryl Garden Dust	Carbaryl (056801/63-25-2)—(10%).
9386-34	9386	AMA-204	Terbutylazine (080814/5915-41-3)—(4%).
9386-42	9386	AMA-2500G	Glutaraldehyde (043901/111-30-8)—(25%).
9386-43	9386	AMA-1500G	Glutaraldehyde (043901/111-30-8)—(15%).
9386-46	9386	AMA-480WB	1,2-Benzisothiazolin-3-one (098901/2634-33-5)—(19%).
9386-47	9386	AMA-80S	1,2-Benzisothiazolin-3-one (098901/2634-33-5)—(19%).
33427-35	33427	Dicropophos Technical	Dicropophos (035201/141-66-2)—(85%).
47000-113	47000	Roberts Dust'M	Gardona (cis-isomer) (083702/22248-79-9)—(3%).
47000-122	47000	RL-2-Rabon Livestock Dust	Gardona (cis-isomer) (083702/22248-79-9)—(3%).
47000-125	47000	Crown All Purpose Livestock and Poultry Dust with Rabon	Gardona (cis-isomer) (083702/22248-79-9)—(3%).
FL-080008	62719	GF-120 NF Naturalyte Fruit Fly Bait	Spinosad (110003/131929-60-7)—(0.02%).
MN-230002	87865	Spin-Aid Herbicide	Phenmedipham (098701/13684-63-4)—(15.9%).
NC-090001	62719	Lorsban Advanced	Chlorpyrifos (059101/2921-88-2)—(40.2%).
NC-090004	62719	Lorsban Advanced	Chlorpyrifos (059101/2921-88-2)—(40.2%).
NC-180002	5481	Parazone 3SL Herbicide	Paraquat dichloride (061601/1910-42-5)—(43.8%).
ND-230001	87865	Spin-Aid Herbicide	Phenmedipham (098701/13684-63-4)—(15.9%).
NY-120006	67690	SP 1908 Aquatic Herbicide	Fluridone (112900/59756-60-4)—(6.3%).
NY-120017	67690	Sonar SRP	Fluridone (112900/59756-60-4)—(5%).
NY-130001	67690	Sonar X	Fluridone (112900/59756-60-4)—(5%).
TX-040027	62719	Lock-On	Chlorpyrifos (059101/2921-88-2)—(22.9%).
TX-080018	62719	Starane Ultra	Fluroxypyr 1-methylheptyl ester (128968/81406-37-3)—(45.52%).
TX-180004	62719	Lorsban Advanced	Chlorpyrifos (059101/2921-88-2)—(40.2%).
TX-220002	100	Gramoxone® SL 2.0	Paraquat dichloride (061601/1910-42-5)—(30.1%).
WY-180001	5481	Parazone 3SL Herbicide	Paraquat dichloride (061601/1910-42-5)—(43.8%).

TABLE 2—PRODUCT REGISTRATION AMENDMENTS TO TERMINATE USES

Registration No.	Company No.	Product name	Active ingredient	Uses to be terminated
8383-3	8383	Sporicidin Disinfectant Solution	Phenol (064001/108-95-2)—(1.56%), Sodium phenate (064002/139-02-6)—(0.06%).	Fogging Use.

Table 3 of this unit includes the names and addresses of record for all registrants of the products in Tables 1

and 2 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA

registration numbers of the products listed above.

TABLE 3—REGISTRANTS OF CANCELLED AND/OR AMENDED PRODUCTS

EPA Company Number	Company Name and Address
100	Syngenta Crop Protection, LLC, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419-8300.
279	FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104.
2749	Aceto Life Sciences, L.L.C., D/B/A Actylis, Agent Name: Product & Regulatory Associates, LLC, 8595 Collier Blvd., Suite 107-51, Naples, FL 34114.

TABLE 3—REGISTRANTS OF CANCELLED AND/OR AMENDED PRODUCTS—Continued

EPA Company Number	Company Name and Address
5481	AMVAC Chemical Corporation, 4695 MacArthur Court, Suite 1200, Newport Beach, CA 92660–1706.
7401	Voluntary Purchasing Groups, Inc., Agent Name: Pyxis Regulatory Consulting, Inc., 535 Dock Street, Suite 211, Tacoma, WA 98402.
8383	Contec, Inc., 525 Locust Grove, Spartanburg, SC 29303.
9386	Kemira Water Solutions, Inc., Agent Name: Ramboll, 4245 North Fairfax Drive, Suite 700, Arlington, VA 22203.
33427	Aceto US, L.L.C., D/B/A/Actylis, Agent Name: Product & Regulatory Associates, LLC, 8595 Collier Blvd., Suite 107–51, Naples, FL 34114.
47000	Chem-Tech, Ltd., 620 Leshner Place, Lansing, MI 48912.
62719	Corteva Agriscience, LLC, 9330 Zionsville Road, Indianapolis, IN 46268.
67690	SePRO Corporation, 11550 N. Meridian Street, Suite 600, Carmel, IN 46032.
87865	Belchim Crop Protection US Corporation, 225 Wilmington West Chester Pike, Suite 200, Chadds Ford, PA 19317

III. Summary of Public Comments Received and Agency Response to Comments

The Agency received one anonymous comment supporting the cancellation of products containing Glutaraldehyde. For these reasons, the Agency does not believe that the comments submitted during the comment period merit further review or a denial of the requests for voluntary cancellation and/or use termination.

IV. Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)(1)), EPA hereby approves the requested cancellations and/or amendments to terminate uses of pesticide registrations identified in Tables 1 and 2 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Tables 1 and 2 of Unit II, are canceled and/or amended to terminate the affected uses. The effective date of the cancellations that are subject of this notice is July 2, 2025. Any distribution, sale, or use of existing stocks of the products identified in Tables 1 and 2 of Unit II, in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI, will be a violation of FIFRA.

V. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of December 17,

2024, (89 FR 102138 (FRL–12320–01–OCSP)). The comment period closed on January 16, 2025.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States, and which were packaged, labeled, and released for shipment prior to the effective date of the action. The existing stocks provision for the products subject to this order is as follows.

For voluntary cancellations, the registrants may continue to sell and distribute existing stocks of products listed in Table 1 until July 2, 2026, which is 1 year after publication of this cancellation order in the **Federal Register**. Thereafter, the registrants are prohibited from selling or distributing products listed in Table 1 of Unit II, except for export in accordance with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Now that EPA has approved product labels reflecting the requested amendments to terminate uses, registrants are permitted to sell or distribute products listed in Table 2 of Unit II, under the previously approved labeling until December 30, 2026, a period of 18 months after publication of the cancellation order in the **Federal Register**, unless other restrictions have been imposed. Thereafter, registrants will be prohibited from selling or distributing the products whose labels include the terminated uses identified in Table 2 of Unit II, except for export consistent with FIFRA section 17 or for proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of canceled products and/or products whose labels include the terminated uses until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that

accompanied, the canceled products and/or terminated uses.

Authority: 7 U.S.C. 136 *et seq.*

Dated: June 26, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2025–12324 Filed 7–1–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2015–0744; FRL–12649–01–OCSP]

Agency Information Collection Activities; Proposed Renewal Collection and Request for Comment; Notification of Substantial Risk of Injury to Health and the Environment Under TSCA Section 8(e)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on the following Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB): “Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e)” (EPA ICR No. 0794.18 and OMB Control No. 2070–0046). This ICR represents a renewal of an existing ICR that is currently approved through April 30, 2026. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before September 2, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number Docket ID No. EPA-HQ-OPPT-2015-0744, online at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Office of Program Support (Mail Code 7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 566-1204; email address: Sleasman.Katherine@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e).

EPA ICR No.: 0794.18.

OMB Control No.: 2070-0046.

ICR Status: This ICR is currently approved through April 30, 2025. Under the PRA, 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 title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 8(e) of the Toxic Substances Control Act (TSCA) states, "any person who manufactures, [imports] processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information." (15 U.S.C. 2607(e)).

EPA receives and screens TSCA section 8(e) submissions covering a large number of chemical substances and mixtures on a wide range of chemical toxicity/exposure information. Although EPA's receipt of TSCA section 8(e) information does not necessarily trigger immediate regulatory action under TSCA or other authorities administered by EPA, all section 8(e) submissions receive screening level evaluations by EPA's Office of Pollution Prevention and Toxics (OPPT) to identify priorities for further Agency action and appropriate referrals to other programs.

TSCA Section 8(e) data on newly discovered chemical hazards/risks is available via EPA's ChemView <https://chemview.epa.gov/chemview>. There is also public outreach and information access to section 8(e) data through the TSCA Public Docket.

In addition, EPA is offering an electronic reporting option for use both by those who are required to submit a notification of substantial risk under section 8(e) and by those who wish voluntarily to submit "For Your Information" (FYI) notices by registering and submitting information electronically using the Agency's Central Data Exchange (CDX), as described below.

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/affected entities: Entities potentially affected by this ICR include North American Industrial Classification System (NAICS) Codes 325—Chemicals and Allied Products Manufacturers and 32411- Petroleum and Coal Products Manufacturing.

Respondent's obligation to respond: Mandatory, as per 15 U.S.C. 2607(e).

Estimated number of potential respondents: 557.

Frequency of response: On occasion.

Total estimated average number of responses for each respondent: 42.

Total estimated burden: hours 27,883 (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated costs: \$ 2,829,860 (per year), includes \$0 annualized capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is an increase in industry reporting burden of 10,248 hours from that currently in the OMB inventory (from 17,635 to 27,883 hours). This reflects an overall increase in the number of section 8(e) submissions, which increased from 343 to 552. This change is an adjustment.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: June 27, 2025.

Nancy B. Beck,

Principal Deputy Assistant Administrator,
Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2025-12325 Filed 7-1-25; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**[EPA-HQ-OPP-2025-0283; FRL-12860-01-OCSPP]****Isocycloseram; Receipt of Application for Emergency Exemption, Solicitation of Public Comment****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

SUMMARY: EPA is announcing a specific exemption request from the New York State Department of Environmental Conservation to use the insecticide isocycloseram (CAS No. 2061933-85-3) to treat up to 2,500 acres of bulb onion to control onion thrips. The applicant proposes the use of a new chemical which has not been registered by EPA. Due to the urgent nature of the emergency, the limited time available to authorize this request in time for the use season, and the recently concluded public participation process for the related proposed Section 3 product registration for the same use, EPA has eliminated the public comment period. Nonetheless, interested parties may still contact the Agency with information about this notice and treatment program.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2025-0283, is available online at <https://www.regulations.gov>. Additional information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (202) 566-2875; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Executive Summary****A. Does this action apply to me?**

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is EPA's authority for taking this action?

Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), at the discretion of the EPA Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the EPA Administrator determines that emergency conditions exist which require the exemption. EPA implementing regulations are set forth in 40 CFR part 166.

C. What action is the Agency taking?

EPA is announcing receipt of a request submitted to EPA under FIFRA section 18. This notice does not constitute a decision by EPA on the application itself. The regulations governing FIFRA section 18 require publication of a notice of receipt of an application for a specific exemption proposing use of a new chemical (*i.e.*, an active ingredient) which has not been registered by EPA.

II. Summary of the Request Received

The New York Department of Environmental Conservation has requested that EPA issue a specific exemption for the use of isocycloseram in bulb onion to control onion thrips. Information in accordance with 40 CFR part 166 was submitted as part of this request.

As part of this request, the applicant asserts that onion thrips is considered the most important insect pest of onion in New York, and emergency conditions exist due to high onion thrip infestations in bulb onion that spread pathogens, causing devastating damage and loss of entire onion fields. New York onion growers face difficulty protecting their crop from significant economic loss due to insufficient tools for season-long control of onion thrip in onion.

The applicant proposes to make a maximum of two applications or up to 160.2 gallons of the unregistered product, A21550 CP, containing 3.33 lb. a.i. of the active ingredient isocycloseram per gallon, to treat a maximum of 2,500 acres of bulb onion requested under this specific exemption during the use season that began June 1 through September 30, 2025. The total

amount of pesticide applied is not to exceed 160.2 gallons of product and can only be used in the following New York counties: Genesee, Madison, Oneida, Orange, Orleans, Oswego, Steuben, Wayne, and Yates.

As noted above, the Agency is eliminating the comment period due to the urgent nature of the emergency situation, limited time available to authorize the request in time for the use season, and the recently concluded public participation process for the related proposed Section 3 product registration for the same use.

Nonetheless, interested parties may still contact the agency with information about this notice and treatment program through the email address under **FOR FURTHER INFORMATION CONTACT**.

Authority: 7 U.S.C. 136 *et seq.*

Dated: June 30, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2025-12348 Filed 7-1-25; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION**[OMB 3060-1285; FR ID 300812]****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 August 1, 2025.

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: 3060–1285.

Title: Compliance with the Non-IP Call Authentication Solution Rules; Robocall Mitigation Database; Use of Third Parties for Authentication.

Form Number: N/A.

Type of Review: Revision of a currently approved information collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 27,400 respondents; 27,400 responses.

Estimated Time per Response: 0.5–3 hours.

Frequency of Response:

Recordkeeping requirement; one-time, on occasion and annual reporting requirements.

Obligation to Respond: Mandatory and required to obtain or retain benefits. Statutory authority for these collections are contained in Sections 227b, 251(e), and 227(e) of the Communications Act of 1934.

Total Annual Burden: 39,450 hours.

Total Annual Cost: No Cost.

Needs and Uses: The Pallone-Thune Telephone Robocall Abuse Criminal Enforcement and Deterrence (TRACED) Act directs the Commission to require all voice service providers to implement STIR/SHAKEN caller ID authentication technology in the internet protocol (IP) portions of their networks and implement an effective caller ID authentication framework in the non-IP portions of their networks. Among other provisions, the TRACED Act also directs the Commission to create extension mechanisms for voice service providers. On September 29, 2020, the Commission adopted its *Call Authentication Trust Anchor Second Report and Order*. See *Call Authentication Trust Anchor*, WC Docket No. 17–97, Second Report and Order, 36 FCC Rcd 1859 (adopted Sept. 29, 2020). The *Second Report and Order* implemented section 4(b)(1)(B) of the TRACED Act, in part, by requiring a voice service provider maintain and be ready to provide the Commission upon request with documented proof that it is participating, either on its own or through a representative, including third party representatives, as a member of a working group, industry standards group, or consortium that is working to develop a non-internet Protocol caller identification authentication solution, or actively testing such a solution. The

Second Report and Order also implemented the extension mechanisms in section 4(b)(5) by, in part, requiring voice service providers to certify in the Robocall Mitigation Database that they have either implemented STIR/SHAKEN or adopted a robocall mitigation program and to describe that program in a filed plan. On May 19, 2022, the Commission adopted similar obligations for gateway providers. See *Advanced Methods to Target and Eliminate Unlawful Robocalls, Call Authentication Trust Anchor*, CG Docket No. 17–59, WC Docket No. 17–97, Fifth Report and Order et al., 37 FCC Rcd 6865 (adopted May 19, 2022). Specifically, like voice service providers, gateway providers were required to maintain and be ready to provide the Commission upon request with documented proof that it is participating, either on its own or through a representative, including third party representatives, as a member of a working group, industry standards group, or consortium that is working to develop a non-internet Protocol caller identification authentication solution, or actively testing such a solution. Gateway providers were also required to implement both STIR/SHAKEN on the IP portions of their networks as well as a robocall mitigation program. They must also certify to their implementation in the Robocall Mitigation Database and describe their robocall mitigation program in a filed plan. On March 16, 2023, the Commission adopted an Order imposing largely the same obligations that applied to gateway providers on a new class of providers: non-gateway intermediate providers. See *Call Authentication Trust Anchor*, Sixth Report and Order and Further Notice of Proposed Rulemaking, WC Docket No. 17–97, 38 FCC Rcd 2573 (adopted March 16, 2023). In that action, the Commission also required all voice service providers to adopt a robocall mitigation program and file a description of that program in the Robocall Mitigation Database, as well as requiring all classes of providers to file additional information in the Robocall Mitigation Database. On May 18, 2023, the Commission adopted an Order modifying some of these requirements. See *Advanced Methods to Target and Eliminate Unlawful Robocalls, Call Authentication Trust Anchor*, CG Docket No. 17–59, WC Docket No. 17–97, Seventh Report and Order et al., 38 FCC Rcd 5404 (adopted May 18, 2023). On November 21, 2024, the Commission strengthened these requirements by establishing rules for the use of third parties in the caller ID authentication

process. To ensure compliance with these rules, the Commission required providers that choose to work with a third party to authenticate calls to do so pursuant to a written agreement and specified that providers must maintain a copy of such agreement for two years following the end or termination of the agreement, and that providers may be required to submit a copy of said agreement to the Commission in connection with a compliance review or enforcement action by the Commission. *Call Authentication Trust Anchor*, WC Docket No. 17–97, Eighth Report and Order, FCC 24–120 (adopted Nov. 21, 2024) (*Eighth Report and Order*). On December 30, 2024, the Commission adopted an Order in a separate proceeding that establishes procedural measures and technical solutions that will ensure and improve the overall quality of submissions to the Robocall Mitigation Database. In doing so, the Commission adopted a requirement that all entities and individuals that register in the Commission’s CORES database update any information submitted to CORES within 10 business days of any change to that information. It also required that all Robocall Mitigation Database filers recertify annually to the accuracy and completeness of the information contained in their filing. *See Improving the Effectiveness of the Robocall Mitigation Database, Amendment of Part 1 of the Commission’s Rules, Concerning Practice and Procedure, Amendment of CORES Registration System*, WC Docket No. 24–213, MD Docket No. 10–234, Report and Order, FCC 24–135 (adopted Dec. 30, 2024) (*RMD Report and Order*).

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2025–12398 Filed 7–1–25; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1192, OMB 3060–1323; FR ID 300735]

Information Collections Being Submitted for Review and Approval to the Office of Management and Budget; Correction

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments; correction.

SUMMARY: The Federal Communications Commission published a document in

the **Federal Register** on June 24, 2025, concerning an information collection request being submitted for review and approval to the Office of Management and Budget. The document inadvertently omitted the preamble captions.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of Tuesday, June 24, 2025 (90 FR 26814), in notice document FR Doc. 2025–11541, [FR ID 300110], appearing on page 26814, in the second column, make the following correction to add the omitted preamble captions to read:

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.”

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before August 1, 2025.

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](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: 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.

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.”

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2025–12393 Filed 7–1–25; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Update to Notice of Financial Institutions for Which the Federal Deposit Insurance Corporation Has Been Appointed Either Receiver, Liquidator, or Manager

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Update listing of financial institutions in liquidation.

SUMMARY: Notice is hereby given that the Federal Deposit Insurance Corporation (Corporation) has been appointed the sole receiver for the following financial institution effective as of the Date Closed as indicated in the listing.

SUPPLEMENTARY INFORMATION: This list (as updated from time to time in the **Federal Register**) may be relied upon as “of record” notice that the Corporation has been appointed receiver for purposes of the statement of policy

published in the July 2, 1992, issue of the **Federal Register** (57 FR 29491). For further information concerning the identification of any institutions that have been placed in liquidation, please visit the Corporation website at www.fdic.gov/bank/individual/failed/banklist.html, or contact the Chief, Receivership Oversight, at RO@fdic.gov or at Division of Resolutions and Receiverships, FDIC, 600 North Pearl Street, Suite 700, Dallas, TX 75201.

INSTITUTIONS IN LIQUIDATION

[In alphabetical order]

FDIC Ref. No.	Bank name	City	State	Date closed
10549	The Santa Anna National Bank	Santa Anna	TX	06/27/2025

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on June 30, 2025.

Jennifer M. Jones,

Deputy Executive Secretary.

[FR Doc. 2025–12350 Filed 7–1–25; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Cancellation of Agency Meeting

Pursuant to the provisions of the “Government in the Sunshine Act” (5 U.S.C. 552b), notice is hereby given that the previously announced Open meeting of the Board of Directors of the Federal Deposit Insurance Corporation scheduled to be held at 10:00 a.m. on Thursday, June 26, 2025, has been *cancelled*.

The Board has decided to act notationally on the agenda items requiring action and therefore will not be holding a Board meeting today.

No earlier notice of this cancellation was practicable.

Dated: June 30, 2025.

(Authority: 5 U.S.C. 552b.)

Dated at Washington, DC, on June 30, 2025.

Federal Deposit Insurance Corporation.

Debra A. Decker,

Executive Secretary.

[FR Doc. 2025–12327 Filed 7–1–25; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board’s Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board’s Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments 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 July 17, 2025.

A. Federal Reserve Bank of Minneapolis (Mark Nagle, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291. Comments can also be sent electronically to MA@mpls.frb.org:

1. *Michael Schmid, Carson, North Dakota*; to join the Schmid Family Control Group, a group acting in concert, to acquire voting shares of Grant County Bancorporation, Inc., and thereby indirectly acquire voting shares of Grant County State Bank, both of Carson, North Dakota.

B. Federal Reserve Bank of Dallas (Lindsey Wieck, Director, Mergers & Acquisitions) 2200 North Pearl Street, Dallas, Texas 75201–2272. Comments can also be sent electronically to Comments.applications@dal.frb.org:

1. *Henry TAW LP, Henry TAW Management LLC* (“TAW Management”), *Racham Investment Group LLC*, (“Racham”), *Robbie S. Campbell, as co-manager of Racham*, and *Richard D. Campbell, individually, and as co-manager of TAW Management and Racham*, all of Midland, Texas; as a group acting in concert (“Campbell Control Group”), to retain voting shares of South Plains Financial, Inc. (“Company”), and thereby indirectly retain voting shares of City Bank (“Bank”), both of Lubbock, Texas.

In addition, Henry Shares LLC, Midland, Texas; to join the Campbell Control Group to acquire voting shares of the Company, and thereby indirectly acquire voting shares of the Bank.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025–12384 Filed 7–1–25; 8:45 am]

BILLING CODE 6210–01–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 August 1, 2025.

A. 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. *RiverBank Bancshares, Inc., Pocahontas, Arkansas*; to become a bank holding company by acquiring RiverBank, also of Pocahontas, Arkansas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025–12376 Filed 7–1–25; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0706]

Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with Environmental Impact Considerations.

DATES: Either electronic or written comments on the collection of information must be submitted by September 2, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 2, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments.

Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–N–2025–0706 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in

its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether

the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Environmental Impact Considerations

OMB Control Number 0910-0322—Extension

FDA is requesting OMB approval for the reporting requirements contained in the FDA collection of information "Environmental Impact Considerations." The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 106(b) of NEPA provides for the preparation of an environmental impact statement (EIS) for a proposed Federal Agency action requiring an environmental document that has a reasonably foreseeable significant effect on the quality of the human environment. Section 106(b) of NEPA further provides for the preparation of an environmental assessment (EA) for a proposed Federal Agency action that does not have a reasonably foreseeable significant effect on the quality of the human environment, or if the significance of such effect is unknown, unless the Agency finds that the proposed Federal Agency action is excluded pursuant to one of the Federal Agency's categorical exclusions (CE). Certain classes of actions that a Federal Agency has determined normally do not, individually or cumulatively, have a significant effect on the quality of the human environment are ordinarily—or categorically—excluded from the requirement to prepare an EA or EIS (see, e.g., section 106(a) of NEPA).

This information collection supports implementation of NEPA, consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service (PHS) Act. Certain requests for FDA action require the preparation of a CE, EA, or EIS. FDA's regulations in part 25 (21 CFR part 25) implement the portions

of NEPA that are relevant to FDA in a manner that is consistent with FDA's authority under the FD&C Act and the PHS Act. These regulations (Environmental Impact Considerations) set forth FDA procedures with regard to NEPA requirements by identifying actions that require the preparation of an environmental document and discussing the preparation of such documents. These regulations also supplement the procedures included in the "HHS General Administration Manual, part 30: Environmental Protection" (45 FR 76519, November 19, 1980).

A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Section 25.15(a) and (d) specifies the procedures for submitting to FDA a claim for a categorical exclusion. Extraordinary circumstances (§ 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded that may result in the need for an EA. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specify the content requirements for EAs for non-excluded actions. Where the Agency finds that no significant environmental effects is expected, a finding of no significant impact is prepared.

This collection of information is used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse events cannot be avoided, the submitted information is used to prepare and circulate to the public an EIS, when applicable, made available through a **Federal Register** document also filed for comment at the Environmental Protection Agency. The final EIS, including the comments received, is reviewed by the Agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact.

Any final EIS would contain, when applicable, additional information gathered by the Agency after the publication of the draft EIS, a copy or a summary of the comments received on

the draft EIS, and the Agency's responses to the comments, including any revisions resulting from the comments or other information. In cases

requiring an EIS, the Agency prepares a record of decision pursuant to § 25.43.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR part 25; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sections 25.20, 25.40, and 25.42; Actions Requiring an EA or an EIS					
Center for Drug Evaluation and Research (CDER)	13	1	13	3,400	44,200
Center for Devices and Radiological Health (CDRH)	66	1	66	3,400	224,400
Center for Biologics Evaluation and Research (CBER)	4	1	4	3,400	13,600
Center for Veterinary Medicine (CVM)	11	1	11	2,160	23,760
Center for Tobacco Products (CTP)	14	1	14	80	1,120
Human Foods Program (HFP)	60	1	60	180	10,800
Subtotal	168		168		317,880
Section 25.15(a) and (d); actions subject to CE					
CDER	3,999	5.0765	20,301	8	162,408
CDRH	66	1	66	6	396
CBER	2,383	3	7,149	8	57,192
CVM	116	6.47	751	3	2,253
HFP	50	1	50	8	400
Subtotal	6,614		28,317		222,649
Total	6,782		28,485		540,529

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

CDER: Under §§ 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i) (21 CFR 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i)), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for CE under § 25.30 or § 25.31, or an EA under § 25.40.

CDRH: Under § 814.20(b)(11) (21 CFR 814.20(b)(11)), premarket approval applications (PMAs) (original PMAs and supplements) must contain a claim for CE under § 25.30 or § 25.34 or an EA under § 25.40.

CBER: Under 21 CFR 601.2(a), biologic license applications (BLAs) as well as INDs (§ 312.23), NDAs (§ 314.50), ANDAs (§ 314.94), and PMAs (§ 814.20) must contain either a claim of CE under § 25.30 or § 25.31 or an EA under § 25.40.

CVM: Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); 21 CFR 514.8(a)(1) supplemental NADAs and ANADAs; 21 CFR 511.1(b)(10) investigational new animal drug applications and generic investigational new animal drug applications, and 21 CFR 571.1(c) food additive petitions (FAPs), 21 CFR 516.129(c)(9) requests for determination of eligibility for indexing, and 21 CFR 510.205(e)(7)

establishment of an import tolerance must contain a claim for CE under § 25.30, § 25.32, or § 25.33, or an EA under § 25.40.

CTP: Under sections 905, 910, and 911 of the FD&C Act (21 U.S.C. 387e, 387j, and 387k), product applications and supplements, premarket tobacco applications (PMTAs), substantial equivalences (SEs), exemption from SEs, and modified risk tobacco product applications must contain a claim for a CE or an EA. Upon evaluation, we have concluded that the majority of the EA burden for tobacco products is accounted for in other information collections currently approved by OMB. The burden we attribute to SEs is currently approved in OMB control number 0910–0673; the burden we attribute to PMTAs is currently approved in OMB control number 0910–0768; and the burden we attribute to SE exemptions is currently approved in OMB control number 0910–0684.

HFP: Under § 25.20, the following actions normally require at least the preparation of an EA, unless the action qualifies for categorical exclusion: establishment by regulation of labeling requirements, a standard, or a monograph, unless categorically excluded in § 25.30(k) or § 25.31(a), (b), (c), (h), (i), or (j), or § 25.32(a) or (p); withdrawal of existing approvals of

FDA-approved articles, unless categorically excluded in § 25.31(d) or (k), § 25.32(m), or § 25.33(g) or (h); approval of food additive petitions and color additive petitions, approval of requests for exemptions for investigational use of food additives, the granting of requests for exemption from regulation as a food additive under 21 CFR 170.39 of this chapter, and allowing notifications submitted under 21 U.S.C. 348(h) to become effective, unless categorically excluded in § 25.32(b), (c), (i), (j), (k), (l), (o), (q), or (r).

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for CEs listed under § 25.32(i) and (q) that the Agency has received in the past 3 years. To avoid counting the burden attributed to § 25.32(o) as zero, we have estimated the burden for this claim of CE at one respondent making one submission a year for a total of one annual submission. The burden for submitting a claim of CE is captured under § 25.15(a) and (d).

Based on a review of the information collection since our last request for OMB approval, we have made adjustments to our burden estimate. Our estimated burden for the information collection reflects an overall increase of

215,125 hours and a decrease of 1,938 responses.

Dated: June 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12307 Filed 7–1–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–0649]

Myelodysplastic Syndromes: Developing Drug and Biological Products for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled “Myelodysplastic Syndromes: Developing Drug and Biological Products for Treatment.” The purpose of this guidance is to assist sponsors in the clinical development of drug and biological products for the treatment of the myelodysplastic syndromes (MDS). Specifically, this guidance addresses FDA’s current thinking regarding the overall development program and clinical trial designs for the development of drug and biological products to support an indication of treatment of MDS. This guidance will focus specifically on development of drug and biological products that are considered disease-modifying and, therefore, will not cover products considered supportive only (e.g., erythropoiesis-stimulating agents). Furthermore, the guidance will not address drug development for MDS/myeloproliferative neoplasms, such as chronic myelomonocytic leukemia, which are considered a separate class of myeloid neoplasms.

DATES: Submit either electronic or written comments on the draft guidance by September 2, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2025–D–0649 for “Myelodysplastic Syndromes: Developing Drug and Biological Products for Treatment.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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

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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Kelly Norsworthy, Center for Drug Evaluation and Research/Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–348–1937; Philip Kurs, Center for Biologics Evaluation and Research, 240–402–7911; or McKenna Tennant, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3423C, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–837–7377, CDRHClinicalEvidence@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled

“Myelodysplastic Syndromes: Developing Drug and Biological Products for Treatment.” The purpose of this guidance is to assist sponsors in the clinical development of drug and biological products for the treatment of MDS. Specifically, this guidance addresses FDA’s current thinking regarding the overall development program and clinical trial designs for the development of drug and biological products to support an indication of treatment of MDS. This guidance is specific to the development of drug and biological products that are considered disease-modifying, and products that are considered supportive therapy (e.g., erythropoiesis-stimulating agents). Furthermore, the guidance will not address drug development for MDS/ myeloproliferative neoplasm overlap symptoms, such as chronic myelomonocytic leukemia, which are considered a separate class of myeloid neoplasms.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Myelodysplastic Syndromes: Developing Drug and Biological Products for Treatment.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 812 have been approved under OMB control number 0910–0078; and the collections of

information pertaining to submission of a biologics license application under section 351(k) of the Public Health Service Act have been approved under OMB control number 0910–0718.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: June 27, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12297 Filed 7–1–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–5142; FDA–2024–E–5273; FDA–2024–E–5274; FDA–2024–E–5275; FDA–2024–E–5276; FDA–2024–E–5277]

Determination of Regulatory Review Period for Purposes of Patent Extension; LIVDELZI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for LIVDELZI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claim that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 2, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 29, 2025. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late,

untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 2, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket Nos. FDA–2024–E–5142; FDA–2024–E–5273; FDA–2024–E–5274; FDA–2024–E–5275; FDA–2024–E–5276; and FDA–2024–E–5277 for “Determination of Regulatory Review Period for Purposes of Patent Extension; LIVDELZI.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those

submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

FOR FURTHER INFORMATION CONTACT: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670)

generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, LIVDELZI (seladelpar lysine) indicated for the treatment of primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. Subsequent to this approval, the USPTO received patent term restoration applications for LIVDELZI (U.S. Patent Nos. 7,301,050; 7,709,682; 9,486,428; 10,272,058; 11,406,611; and 11,596,614) from Gilead Sciences, Inc. (Agent of Janssen Pharmaceutica, N.V.) and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated March 17, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of LIVDELZI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for

LIVDELZI is 6,969 days. Of this time, 6,724 days occurred during the testing phase of the regulatory review period, while 245 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* July 18, 2005. The applicant claims July 19, 2005, as the date the investigational new drug application (IND) became effective.

However, FDA records indicate that the IND effective date was July 18, 2005, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 14, 2023. FDA has verified the applicant’s claim that the new drug application (NDA) for LIVDELZI (NDA 217899) was initially submitted on December 14, 2023.

3. *The date the application was approved:* August 14, 2024. FDA has verified the applicant’s claim that NDA 217899 was approved on August 14, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 386, 491, 1,090, 1,244, or 1,826 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket

No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-12345 Filed 7-1-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-E-0447; FDA-2024-E-0446; FDA-2024-E-0445; FDA-2024-E-0444]

Determination of Regulatory Review Period for Purposes of Patent Extension; [TOTAL POSTERIOR SPINE SYSTEM (TOPS SYSTEM)]

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for TOTAL POSTERIOR SPINE SYSTEM (TOPS SYSTEM) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 2, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 29, 2025. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 2, 2025. Comments received by mail/hand delivery/courier (for

written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA-2024-E-0447; FDA-2024-E-0446; FDA-2024-E-0445; FDA-2024-E-0444 for Determination of Regulatory Review Period for Purposes of Patent Extension; TOTAL POSTERIOR SPINE SYSTEM (TOPS SYSTEM). Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential

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

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

FOR FURTHER INFORMATION CONTACT: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240-402-6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a

product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device TOTAL POSTERIOR SPINE SYSTEM (TOPS SYSTEM). TOTAL POSTERIOR SPINE SYSTEM (TOPS SYSTEM) is a motion-preserving spinal implant that is inserted into the lumbar spine via pedicle screws. TOTAL POSTERIOR SPINE SYSTEM (TOPS SYSTEM) is intended to stabilize the spine following a lumbar decompression without rigid fixation. It is indicated for patients between 35 and 80 years of age with symptomatic degenerative spondylolisthesis up to Grade 1 with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum and/or of the scarring facet joint capsule at one level from L3 to L5. Subsequent to this approval, the USPTO received a patent term restoration application for TOTAL POSTERIOR SPINE SYSTEM (TOPS SYSTEM) (U.S. Patent Nos. 7,811,322; 7,811,323; 7,833,272; and 8,262,699) from Premia Spine Ltd., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated October 9, 2024, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of TOTAL POSTERIOR SPINE SYSTEM (TOPS SYSTEM) represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for

TOTAL POSTERIOR SPINE SYSTEM is 6,147 days. Of this time, 5,662 days occurred during the testing phase of the regulatory review period, while 485 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* August 18, 2006. FDA has verified the applicant's claim that the date the investigational device exemption for human tests to begin, as required under section 520(g) of the FD&C Act, became effective August 18, 2006.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* February 16, 2022. FDA has verified the applicant's claim that the premarket approval application (PMA) for TOTAL POSTERIOR SPINE SYSTEM (PMA P220002) was initially submitted February 16, 2022.

3. *The date the application was approved:* June 15, 2023. FDA has verified the applicant's claim that PMA P220002 was approved on June 15, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket

No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12339 Filed 7–1–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–3582; FDA–2024–E–3583; FDA–2024–E–3584; FDA–2024–E–3585; FDA–2024–E–3586; FDA–2024–E–3587]

Determination of Regulatory Review Period for Purposes of Patent Extension; WINREVAIR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for WINREVAIR and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by September 2, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 29, 2025. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 2, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be

considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket Nos. FDA-2024-E-3582; FDA-2024-E-3583; FDA-2024-E-3584; FDA-2024-E-3585; FDA-2024-E-3586; FDA-2024-E-3587 for "Determination of Regulatory Review Period for Purposes of Patent Extension; WINREVAIR." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential

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

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

FOR FURTHER INFORMATION CONTACT: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240-402-6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a

product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product WINREVAIR (sotatercept-csrk). WINREVAIR is indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class and reduce the risk of clinical worsening events. Subsequent to this approval, the USPTO received patent term restoration applications for WINREVAIR (U.S. Patent Nos. 7,612,041; 7,951,771; 10,695,405; 10,722,558; 10,946,067; 11,065,303) from Acceleron Pharma Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated October 9, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of WINREVAIR represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for WINREVAIR is 5,452 days. Of this time, 5,207 days occurred during the testing phase of the regulatory review period, while 245 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* April 24, 2009. The applicant claims April 26, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 24, 2009, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* July 26, 2023. FDA has verified the applicant's claim that the biologics license application (BLA) for WINREVAIR (BLA 761363) was initially submitted on July 26, 2023.

3. *The date the application was approved:* March 26, 2024. FDA has verified the applicant's claim that BLA 761363 was approved on March 26, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 255 days, 1,826 days, or 1,827 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630

Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12341 Filed 7–1–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–0158]

Determination of Regulatory Review Period for Purposes of Patent Extension; [CHOCOLATE TOUCH (PACLITAXEL DRUG COATED PTA BALLOON CATHETER)]

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for CHOCOLATE TOUCH (PACLITAXEL DRUG COATED PTA BALLOON CATHETER) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 2, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 29, 2025. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 2, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2024–E–0158 for Determination of Regulatory Review Period for Purposes of Patent Extension; CHOCOLATE TOUCH (PACLITAXEL DRUG COATED PTA BALLOON CATHETER). Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

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

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

FOR FURTHER INFORMATION CONTACT: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 240-402-6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the

amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device CHOCOLATE TOUCH (PACLITAXEL DRUG COATED PTA BALLOON CATHETER). CHOCOLATE TOUCH (PACLITAXEL DRUG COATED PTA BALLOON CATHETER) is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation of de novo or restenotic lesions up to 180 mm in length in native femoral or popliteal arteries with reference vessel diameters of 4.0 mm to 6.0 mm. Subsequent to this approval, the USPTO received a patent term restoration application for CHOCOLATE TOUCH (PACLITAXEL DRUG COATED PTA BALLOON CATHETER) (U.S. Patent No. 9,179,936) from TriReme Medical, LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 7, 2024, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of CHOCOLATE TOUCH (PACLITAXEL DRUG COATED PTA BALLOON CATHETER) represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for CHOCOLATE TOUCH (PACLITAXEL DRUG COATED PTA BALLOON CATHETER) is 2,242 days. Of this time, 1,930 days occurred during the testing phase of the regulatory review period, while 312 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* September 16, 2016. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on September 15, 2016. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on September 16, 2016, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* December 28, 2021. The applicant claims December 22, 2021, as the date the premarket approval application (PMA) for CHOCOLATE TOUCH (PACLITAXEL DRUG COATED PTA BALLOON CATHETER) (PMA P210039) was initially submitted. However, FDA records indicate that PMA P210039 was submitted on December 28, 2021.

3. *The date the application was approved:* November 4, 2022. FDA has verified the applicant's claim that PMA P210039 was approved on November 4, 2022.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,235 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-12340 Filed 7-1-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2024-E-0209 and FDA-2024-E-0210]

Determination of Regulatory Review Period for Purposes of Patent Extension; ELREXFIO; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on May 12, 2025. The document, entitled “Determination of Regulatory Review Period for Purposes of Patent Extension; ELREXFIO,” announced the determination of the regulatory review period for ELREXFIO (elranatamab-bcmm) for purposes of patent extension. The document was published with only one of two docket numbers. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Jack Dan, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240-402-6940.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Monday, May 12, 2025 (90 FR 20177), in FR Doc. 2025-08256, the following corrections are made:

1. On page 20177, in the second column of the header of the document, “Docket No. FDA-2024-E-0210” is corrected to read “Docket Nos. FDA-2024-E-0209 and FDA-2024-E-0210.”

2. On page 20177, in the **ADDRESSES** section, in the third column under Written/Paper Submissions, in the second and third lines of the Instructions paragraph, “Docket No. FDA-2024-E-0210” is corrected to read

“Docket Nos. FDA-2024-E-0209 and FDA-2024-E-0210.”

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-12343 Filed 7-1-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0426]

Agency Information Collection Activities; Proposed Collection; Comment Request; Agreement for Shipment of Devices for Sterilization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection related to shipment of nonsterile devices that are to be sterilized elsewhere or are shipped to other establishments for further processing, labeling, or repacking.

DATES: Either electronic or written comments on the collection of information must be submitted by September 2, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 2, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments.

Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2025-N-0426 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Agreement for Shipment of Devices for Sterilization.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in

its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Lansdowne St., North Bethesda, MD 20852, 301–796–8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150

OMB Control Number 0910–0131—Extension

This information collection helps to support FDA regulations. Under

sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations at § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms.

Under § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) contact information of the firms involved and the identification of the signature authority of the shipper and receiver, (2) instructions for maintaining accountability of the number of units in each shipment, (3) acknowledgment that the devices that are nonsterile are being shipped for further processing, and (4) specifications for sterilization processing. This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices (see § 801.150(a)(2)). The respondents to this collection of information are device manufacturers and contract sterilizers.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR part; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Record retention, 801.150(a)(2)	218	37.5	8,175	.5 (30 minutes)	4,088

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA’s estimate of the reporting burden is based on data obtained from industry in recent years. It is estimated that each of the firms subject to this requirement prepares an average of 37.5 written agreements each year. This estimate varies greatly, from 1 to 218, because some firms provide sterilization services on a part-time basis for only 1 customer, while others are large facilities with many customers. The

average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements imposed by this regulation. The written

agreement generally also includes contractual agreements that are a usual and customary business practice. The recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the records required under the third-party disclosure section of this collection.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR part; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Agreement and labeling requirements, 801.150(e)	218	37.5	8,175	4	32,700

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 24, 2025.
Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2025–12306 Filed 7–1–25; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2024–E–0402]

Determination of Regulatory Review Period for Purposes of Patent Extension; REBYOTA

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for REBYOTA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by September 2, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 29, 2025. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until

11:59 p.m. Eastern Time at the end of September 2, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2024–E–0402 for “Determination of Regulatory Review Period for Purposes of Patent Extension; REBYOTA.”

Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

FOR FURTHER INFORMATION CONTACT: Jack Dan, Office of Regulatory Policy, Food

and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240-402-6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product REBYOTA (fecal microbiota, live-jslm). REBYOTA is indicated for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI. Subsequent to this approval, the USPTO received a patent term restoration application for REBYOTA (U.S. Patent No. 9,675,648) from Rebiotix, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 9, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory

review period and that the approval of REBYOTA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for REBYOTA is 3,461 days. Of this time, 3,095 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* June 11, 2013. The applicant claims April 21, 2013, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 11, 2013, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* November 30, 2021. The applicant claims May 3, 2021, as the date the biologics license application (BLA) for REBYOTA (BLA 125739) was initially submitted. However, FDA records indicate that BLA 125739 was submitted on November 30, 2021 when a complete application was received.

3. *The date the application was approved:* November 30, 2022. FDA has verified the applicant's claim that BLA 125739 was approved on November 30, 2022.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 479 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must

comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-12342 Filed 7-1-25; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0339]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mitigation Strategies To Protect Food Against Intentional Adulteration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on collections of information applicable to mitigation strategies to protect food against intentional adulteration.

DATES: Either electronic or written comments on the collection of information must be submitted by September 2, 2025.

ADDRESSES: You may submit comments as follows. Please note that late,

untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 2, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2025-N-0339 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Mitigation Strategies To Protect Food Against Intentional Adulteration." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

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

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

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Mitigation Strategies To Protect Food Against Intentional Adulteration—21 CFR Part 21

OMB Control Number 0910-0812—Extension

This information collection helps support the implementation of statutory and regulatory requirements intended to ensure the safety of food. Section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g) governs the assessment and evaluation of hazard analyses and risk-based preventive controls intended to provide assurances that food is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342). Similarly, section 419 of the FD&C Act (21 U.S.C. 350h) establishes standards for produce safety, and section 420 of the FD&C Act (21 U.S.C. 350i) requires the mitigation against intentional adulteration of high-risk foods (exempting farms except for farms that produce milk).

Agency regulations in part 121 (21 CFR part 121) establish requirements applicable to owners, operators, or agents in charge of domestic or foreign food facilities that manufacture/process, pack, or hold food for consumption in the United States. The regulations, require the preparation, retention and

maintenance, and implementation of written mitigation strategies and procedures for defense monitoring, corrective actions, and food defense verification procedures.

To help facilitate the submission to FDA of required information and reduce burden on respondents, we have developed resources, including an “FDA Food Defense Plan Builder,” (version 2.0) available at <https://www.fda.gov/food/food-defense/food-defense-tools-educational-materials>. Other resources made available to respondents include two draft guidance documents entitled “Mitigation Strategies To Protect Food Against

Intentional Adulteration: Draft Guidance for Industry” (84 FR 8103, March 6, 2019), and “Supplemental Draft Guidance for Industry: Mitigation Strategies To Protect Food Against Intentional Adulteration” (85 FR 8599, February 14, 2020), which are available at <https://www.fda.gov/food/food-defense>. The guidance documents are intended to assist respondents in developing and implementing requisite elements of a food defense plan. All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time. Finally, we developed the

small entity compliance guide entitled “Mitigation Strategies To Protect Food Against Intentional Adulteration” (82 FR 40484, August 25, 2017), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-mitigation-strategies-protect-food-against-intentional-adulteration>.

Description of Respondents: The respondents to this information collection are manufacturers, processors, packers, and holders of retail food products marketed in the United States.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Information collection activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption requests for very small businesses; § 121.5	18,080	1	18,080	0.5 (30 minutes)	9,040

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Food Defense Plan; § 121.126	3,247	1	3,247	23	74,681
Actionable Process Steps; § 121.130	9,759	1	9,759	20	195,180
Mitigation Strategies; § 121.135(b)	9,759	1	9,759	20	195,180
Monitoring, Corrective Actions, Verification; §§ 121.140(a), 121.145(a)(1), and 121.150(b).	9,759	1	9,759	175	1,707,825
Training; § 121.4	367,203	1	367,203	0.67 (40 minutes)	246,026
Records; §§ 121.305 and 121.310	9,759	1	9,759	10	97,590
Total					2,516,482

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12308 Filed 7–1–25; 8:45 am]

BILLING CODE 4164–01–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; Investigator initiated Program Project Applications.

Date: July 29–30, 2025.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vanitha Sundaresa Raman, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9823, Rockville, MD 20852, 301–761–7949, vanitha.raman@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Development of Radiation/Nuclear Medical

Countermeasures (MCMs) And Biodosimetry Devices.

Date: July 31–August 1, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sandip Bhattacharyya, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9823, Rockville, MD 20852, sandip.bhattacharyya@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AD/ADRD- and Aging-Related Outcomes.

Date: August 5, 2025.

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.

Meeting Format: Virtual Meeting.

Contact Person: Surojeet Sengupta, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Neurological Disorders and Stroke, 6001 Executive

Boulevard, Room 5134, Bethesda, MD 20892, (301) 496-9223, surojeet.sengupta@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular and Cellular Topics in Basic Neuroscience.

Date: August 5–6, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, Bethesda, MD 20892, (301) 827-4471, ramadanir@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Miniaturization and Automation of Tissue Chip Systems (MATCHS).

Date: August 5, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Bruce Sundstrom, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G11A, National Institutes of Health/ NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892-9834, (240) 669-5045, sundstromj@niaid.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Career Development and Research Education Programs.

Date: August 5, 2025.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Chee Lim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128, Bethesda, MD 20892, (301) 435-1850, limc4@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Endocrine and Metabolic Systems.

Date: August 6, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Zhuqing Li, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3G41B, National Institutes of Health/ NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892-9834, (240) 669-5068, zhuqing.li@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel;

Fellowships: Aging, Neurodegeneration, and Neurotoxicology.

Date: August 6–7, 2025.

Time: 9:30 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Rahat Rani Khan, Ph.D., Scientific Review Officer, Office of Grants Management and Scientific Review, National Center for Advancing Translational Sciences, 6701 Democracy Blvd., Rm. 1078, Bethesda, MD 20892, 301-594-7319, Khanr2@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular Genetics and Genomics

Date: August 6–7, 2025.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Dharmendar Rathore, Ph.D., Chief, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute on Drug Abuse, NIH 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 402-6965, dharmendar.rathore@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Topics in Infectious Disease.

Date: August 6, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jennifer Hartt Meyers, Ph.D., Scientific Review Program, DEA/ NIAID/NIH/DHHS, 5601 Fishers Lane, MSC-9823, Rockville, MD 20852, 301-761-6602, jennifer.meyers@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: June 30, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-12378 Filed 7-1-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive, Inter-Institutional Agreement-Institution Lead: Generation of Antigen-Specific T and B Cells Using Engineered Commensals

AGENCY: National Institutes of Health, National Institute of Allergy and Infectious Diseases, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive, Inter-Institutional Agreement-Institution Lead to CZ Biohub SF, LLC (“CZB”), located in San Francisco, California, in its rights to the technologies and patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, on or before July 17, 2025 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive, Inter-Institutional Agreement-Institution Lead should be directed to: Jonathan Motley, Ph.D., Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, 6D29, MSC9804, Rockville, MD 20852-9804, phone number 240-669-5209, or jonathan.motley@nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to CZB: United States Provisional Patent Application Serial No. 63/588,398, filed October 6, 2023, the title of which is “Generation Of Antigen-Specific T And B Cells Using Engineered Commensals” (HHS Reference No. E-047-2024-0-US-01); and PCT Application Number PCT/US24/50039, filed October 4, 2024 (HHS Reference No. E-047-2024-0-PC-01), the title of which is “Generation Of Antigen-Specific T And B Cells Using Engineered Commensals”.

The patent rights to this technology have been assigned to CZB, The Board Of Trustees Of The Leland Stanford

Junior University, and the Government of the United States of America as represented by the Secretary, Department of Health & Human Services.

The prospective patent license will be for the purpose of consolidating the patent rights to CZB, for the development and commercialization of the technology.

Consolidation of these co-owned rights is intended to expedite development of the technology, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200–212.

The prospective interinstitutional agreement may include an exclusive license for NIAID's rights in these jointly owned patents. It will be sublicensable, and any sublicenses granted by CZB will be subject to the provisions of 37 CFR part 404.

In the subject technology, the inventors describe a method of modifying commensal bacteria to carry heterologous antigenic fragments and the use of these modified bacterial cells to specifically stimulate or reduce a host's immune response by modulating the response of T- and B-cells or antigen-presenting cells (APCs). To modify the bacterial cells, the inventors describe the use of genetic tools and fusion proteins, transpeptidases, or by using covalent bonding of the antigenic fragment to extracellular proteins found on the surface. The modified bacteria are then applied to the skin or mucosal membranes of a target mammal (including humans). Other applications could include the delivery of molecules encased in lipid nanoparticles by adhering them to the surface of the commensal bacteria via the modification methods described above.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

Complete license applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as

required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: June 30, 2025.

Surekha Vathyam,

Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2025–12381 Filed 7–1–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT:

Brian Bailey at 240–669–5128, or bbailey@mail.nih.gov. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION:

Technology description follows:

EV–D68 Monoclonal Antibodies Isolated From Immunized Rhesus Macaques

Description of Technology:

Enterovirus D68 (EV–D68) has been linked to the widespread outbreaks of respiratory illness and acute flaccid myelitis (AFM) in the United States and Europe in 2014, 2016, and 2018. Although EV–D68 is now the most frequently encountered enterovirus (41.1% of cases), with an estimated global prevalence of 4%, there are no specific, FDA-approved therapeutic interventions targeting this virus.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Disease (NIAID)

have identified four monoclonal antibodies that potently bind and neutralize multiple subclades of EV–D68, including B3 and A2 variants. Animal studies have indicated that these Rhesus macaque-derived monoclonal antibodies (mAbs) are likely to confer protection against respiratory illness in young children (particularly those under age 5) and in individuals with respiratory or immunocompromising conditions. Analyses conducted using standard techniques such as cryo-EM have enabled the inventors to further characterize the epitopes of two unique EV–D68-specific antibodies, suggesting the value of this technology for developing multi-specific approaches that confer broad protection against EV–D68.

Humanization and combination of these mAbs with other antibodies exhibiting unique epitope specificities may prove beneficial for therapeutic or prophylactic purposes, especially within the context of a broader pandemic preparedness program. Further, these antibodies could be incorporated into diagnostic assays/kits for the rapid and accurate detection of EV–D68 in clinical or non-clinical settings.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

- Prevention or treatment of EV–D68 infection
- Development of diagnostic assays for rapid, accurate EV–D68 detection in clinical and non-clinical settings

Competitive Advantages:

- Development of prophylactic or therapeutic interventions against EV–D68 that effectively induce broad protection against multiple circulating subclades

Development Stage: Preclinical

Inventors: Tracy Ruckwardt, Daniel Moss, Peter Krug, Masaru Kanekiyo (all of NIAID VRC)

Relevant Publications: Krug et al. EV–D68 virus-like particle vaccines elicit cross-clade neutralizing antibodies that inhibit infection and block dissemination. *Sci. Adv.* 2023;9:eadg6076. DOI:10.1126/sciadv.adg6076

Intellectual Property: HHS Reference No. E–041–2024; Provisional Patent Application 63/640,619, filed on April 30, 2024, and PCT Patent Application No. PCT/US2025/027110, filed on April 30, 2025.

Licensing Contact: To license this technology, please contact Brian Bailey

at 240-669-5128, or bbailey@mail.nih.gov and reference E-041-2024.

Dated: June 20, 2025.

Surekha Vathyam,

Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2025-12391 Filed 7-1-25; 8:45 am]

BILLING CODE 4140-01-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; Neurodevelopment and Disorders.

Date: August 5-6, 2025.

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.

Meeting Format: Virtual Meeting.

Contact Person: Chi-Tso Chiu, Ph.D., Scientific Review Officer, Scientific Review Branch (SRB), Eunice Kennedy Shriver National Institute of Child Health & Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm. 2127B, Bethesda, MD 20817, (301) 435-7486, chiuc@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Clinical Trial: Topics in Immunology, Viral, Bacterial, and Parasitic Disease.

Date: August 5, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3F40A, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892-9834, (240) 669-5035, robert.unfer@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: BRAIN development and validation of novel tools for cell-specific and circuit-specific processes.

Date: August 5, 2025.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1066, Bethesda, MD 20892-4878, (301) 435-0813, victor.henriquez@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Research Career Development Awards SEP B.

Date: August 6, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9606, Bethesda, MD 20892-9606, 301-443-4525, steinerr@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biomedical Imaging Approaches in Cancer Research.

Date: August 6, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vera A Cherkasova, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Room 2137B, Bethesda, MD 20892, (240) 731-6040, vera.cherkasova@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cellular and Molecular Aspects of the Blood-Brain Barrier and Neurovascular System and Therapeutic Strategies.

Date: August 7, 2025.

Time: 9:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Eric S. Tucker, Ph.D., Scientific Review Officer, Scientific Review Branch, Neuroscience Center, 6001 Executive Blvd., Rockville, MD 20852, (301) 827-0799, eric.tucker@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member

Conflict: Topics in HIV Comorbidities, Coinfections and Associated Cancers.

Date: August 7, 2025.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Caitlin Elizabeth Angela Moyer, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 443-4577, caitlin.moyer@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA: Clinical Care and Interventions for Substance Use Disorders, Prevention, and Treatment of Addiction.

Date: August 11-12, 2025.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Marisa Srivareerat, Ph.D., Scientific Review Officer, Scientific Review Branch, Office of Extramural Policy, National Institute on Drug Abuse, NIH, 11601 Landsdown Street, 3WF Room 09C49, Bethesda, MD 20892, (301) 435-1258, marisa.srivareerat@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-23-124: Genomic Community Resources (U24).

Date: August 11, 2025.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Maryam Rohani, Ph.D., Scientific Review Officer, NIAID Immunology Review Branch, BG 5601 Fishers Lane, Rm. 3G56, Rockville, MD 20852, (301) 761-6656, maryam.rohani@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: NIA Program Project Applications (P01) Review.

Date: August 12, 2025.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Eric S. Tucker, Ph.D., Scientific Review Officer, Scientific Review Branch, Neuroscience Center, 6001 Executive Blvd., Rockville, MD 20852, (301) 827-0799, eric.tucker@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: June 30, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–12382 Filed 7–1–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2006–26514]

Revision of Agency Information Collection Activity Under OMB Review: Physical Surface Transportation Security

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0051, abstracted below for OMB review and approval a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the information collection and its expected burden and involves information to validate compliance with regulatory requirements aimed at enhancing physical surface transportation security, including security coordinator information, reporting of significant security concerns, submission of location and shipping information, chain of custody and control requirements, security training programs, and training records.

DATES: Send your comments by August 1, 2025. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” and by using the find function.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6011; telephone (571) 227–2062; email TSAPRA@tsa.dhs.gov.

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on April 21, 2025, 90 FR 16697. TSA did not receive any comments on the notice.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), 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 OMB control number. The ICR documentation will be available at <https://www.reginfo.gov> upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency’s estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Physical Surface Transportation Security.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0051.

Form(s): NA.

Affected Public: Freight rail, passenger rail, and shippers/receivers of certain hazardous materials.

Abstract: TSA is consolidating two overlapping OMB Control Numbers, 1652–0051 Rail Transportation Security, which collects and uses information collected under 49 CFR parts 1570 and 1580, with 1652–0066 Security Training Program for Surface Transportation Employees, which collects and uses information collected under 49 CFR parts 1570, 1580, 1582, and 1584. In light of the revision to consolidate the collections, TSA will request that OMB discontinue OMB Control Number 1652–0066 Security Training Program for Surface Transportation Employees and will change the title of the collection under OMB Control Number 1652–0051 from “Rail Transportation

Security” to “Physical Surface Transportation Security.”

These regulations require the collection of information to implement the regulatory requirements for the following: submission and amendment of security training program; security training recordkeeping; submission of security coordinator information; reporting of significant security concerns; submission of location and shipping information; and chain of custody and control requirements.

Estimated Annual Number of Respondents: 2,070.

Estimated Annual Burden Hours: 66,995.

Dated: June 30, 2025.

Christina A. Walsh,

Paperwork Reduction Act Officer, Information Technology, Transportation Security Administration.

[FR Doc. 2025–12395 Filed 7–1–25; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Extension of Agency Information Collection Activity Under OMB Review: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0058, abstracted below, to OMB for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The information collection activity provides a means to gather qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with TSA’s commitment to improving service delivery.

DATES: Send your comments by August 1, 2025. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this

particular information collection by selecting “Currently under Review—Open for Public Comments” and by using the find function.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6011; telephone (571) 227–2062; email TSAPRA@dhs.gov.

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on December 5, 2024 (89 FR 96660). TSA received no comments on the notice.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), 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 OMB control number. The ICR documentation will be available at <https://www.reginfo.gov> upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

- (1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agency’s estimate of the burden;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Type of Request: Extension.

OMB Control Number: 1652–0058.

Form(s): NA.

Affected Public: Individuals, Households, Businesses, Organizations, and State, Local or Tribal Governments.

Abstract: The information collection activity provides a means to gather qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Executive Order 12862 commitment to improving service delivery.

This collection will allow for ongoing, collaborative, and actionable communications between TSA and its customers and stakeholders. TSA believes qualitative feedback from customers and stakeholders provides useful insights on their perceptions, experiences, opinions, and expectations regarding TSA products or services, provides TSA with an early warning of issues with service, and focuses attention on areas where changes regarding communication, training, or operations might improve delivery of products or services.

The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered by TSA. If this information is not collected, vital feedback from customers and stakeholders on TSA’s services will be unavailable.

As a general matter, this information collection will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature. Information gathered is intended to be used solely within TSA general service improvement and program management purposes and is not intended for release outside of TSA (if released, TSA will indicate the qualitative nature of the information). Feedback collected under this generic clearance provides useful qualitative information, but it does not yield data that can be generalized to the overall population. Qualitative information is not designed or expected to yield statistically reliable or actionable results; it will not be used for quantitative information collections. Depending on the degree of influence the results are likely to have, there may be future information collection submissions for other generic mechanisms that are designed to yield quantitative results.

Below we provide TSA’s projected average estimates for the next 3 years:

Estimated Number of Annual Respondents: 7,094,500.

Estimated Annual Burden Hours: 1,180,050.

Dated: June 30, 2025 .

Christina A. Walsh,
Paperwork Reduction Act Officer,
Information Technology, Transportation
Security Administration.

[FR Doc. 2025–12361 Filed 7–1–25; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6550–N–01]

Rescission of Office of the Assistant Secretary for Public and Indian Housing; Voter Registration Notice

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notification of rescission.

SUMMARY: The Department of Housing and Urban Development announces that it is rescinding a March 7, 1996, **Federal Register** notice that provided guidance on efforts by Public Housing Agencies to promote voter registration in Public and Indian Housing.

DATES: *Effective Date:* July 2, 2025.

FOR FURTHER INFORMATION CONTACT: Nicholas Bilka, Office of Policy, Programs, and Legislative Initiatives, Department of Housing and Urban Development, 451 Seventh Street SW, Room 3178, Washington, DC 20410. Telephone number (202) 402–5449 (This is not a toll-free number.) HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as from individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

SUPPLEMENTARY INFORMATION: On March 7, 1996, HUD published a guidance document in the **Federal Register** entitled “*Office of the Assistant Secretary for Public and Indian Housing; Voter Registration Notice*” (61 FR 9190). This Notice rescinds the March 7, 1996, notice in its entirety, effective immediately.

Benjamin Hobbs,

Principal Deputy Assistant Secretary, Public and Indian Housing.

[FR Doc. 2025–12298 Filed 7–1–25; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–OC–2025–N029;
FXGO16600926000–256–FF09X60000]

Hunting and Wildlife Conservation Council Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of virtual meeting.

SUMMARY: The U.S. Fish and Wildlife Service (Service) gives notice of a virtual meeting of the Hunting and Wildlife Conservation Council (Council), in accordance with the Federal Advisory Committee Act.

DATES:

Meeting: The Council will meet on Wednesday, July 23, 2025, from 2 p.m. to 4 p.m. (eastern time).

Registration: Registration to attend or participate in the meeting is required. The registration deadline is Wednesday, July 16, 2025. To register, please contact the Designated Federal Officer (DFO) (see **FOR FURTHER INFORMATION CONTACT**).

Public Comment: If you wish to provide oral public comment or provide a written comment for the Council to consider, contact the DFO (see **FOR FURTHER INFORMATION CONTACT**) no later than Wednesday, July 16, 2025.

Accessibility and Other Accommodations: The deadline for accommodation requests is Wednesday, July 16, 2025. For more information, please see “Requests for Accommodations,” below.

ADDRESSES: The meeting will be held via a virtual meeting platform. To register and receive the web address and telephone number for virtual participation, contact the DFO (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Douglas Hobbs, DFO, 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:

Background

Under the authority of the Federal Advisory Committee Act (5 U.S.C. Ch. 10), the Hunting and Wildlife Conservation Council (Council) was established to further implementation of the provisions of the Fish and Wildlife Act of 1956 (16 U.S.C. 742a *et seq.*), the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701-1785), the National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd-ee), other statutes applicable to specific Department of the Interior bureaus, and Executive Order 13443 of August 16, 2007, “Facilitation of Hunting Heritage and Wildlife Conservation” (72 FR 46537, August 20, 2007). The Council’s purpose is to

provide recommendations to the Federal Government, through the Secretary of the Interior and the Secretary of Agriculture, regarding policies and endeavors that (a) benefit wildlife resources; (b) encourage partnership among the public, sporting conservation organizations, and Federal, State, Tribal, and territorial governments; and (c) benefit fair-chase recreational hunting and safe recreational shooting sports.

Meeting Agenda

Among other business to be addressed by the Council, the meeting will include comments from new leadership team members at both the Department of the Interior and Department of Agriculture, an update from U.S. Fish and Wildlife Service staff on continued implementation of its initiative to incentivize the use of lead-free ammunition on the lands of the National Wildlife Refuge System and other refuge-related issues, and an update on Department of Agriculture issues.

The Council will also hear public comment if members of the public make such requests. The final agenda and other related meeting information will be available on the Council website, <https://www.fws.gov/program/hwcc>.

Public Input

Depending on the number of people who want to comment and the time available, the amount of time for individual oral comments may be limited. Interested parties should contact the DFO in writing (see **FOR FURTHER INFORMATION CONTACT**) for placement on the public speaker list for this meeting. Requests to address the Council during the meeting will be accommodated in the order the requests are received. Registered speakers who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, may submit written statements to the DFO up to 30 days following the meeting.

Requests for Accommodations

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the DFO in the **FOR FURTHER INFORMATION CONTACT** section of this notice by July 16, 2025, to give the U.S. Fish and Wildlife Service sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information on any comments you might have about this notice, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

5 U.S.C. Ch. 10.

Nancy S. Monroe,

Acting Assistant Director, Office of Communications.

[FR Doc. 2025-12385 Filed 7-1-25; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Safran S.A., et al.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America v. Safran S.A., et al.*, Civil Action No. 1:25-cv-01897. On June 17, 2025, the United States filed a Complaint alleging that Safran S.A.’s proposed acquisition of Collins Aerospace’s actuation and flight control business from RTX Corporation would violate Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed Final Judgment, filed at the same time as the Complaint, requires Safran S.A. to divest its North American actuation business, including THSAs and secondary flight control actuators, and its Canada-based electronic control units.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division’s website at <http://www.justice.gov/atr> and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be submitted in English and directed to Soyoung Choe, Acting Chief, Defense, Industrials, and Aerospace Section, Antitrust Division, Department of Justice, 450 Fifth Street NW, Suite 8700, Washington, DC 20530 (email address: ATR.DIA-Information@usdoj.gov).

Suzanne Morris,

Deputy Director of Civil Enforcement Operations, Antitrust Division.

United States District Court for the District Of Columbia

United States of America, 450 Fifth Street NW, Washington, DC 20530 Plaintiff, v. Safran, S.A. 2, bd du General Martial-Valin Paris, France 75015, Safran, USA, INC., 700 South Washington Street, Suite 250, Alexandria, VA 22314, and RTX Corporation, 1000 Wilson Blvd, Arlington, VA 22209 Defendants.

No. 1:25-cv-01897-CRC

Judge: Christopher R. Cooper

Complaint

Safran S.A., Safran USA, Inc. (combined "Safran") and RTX Corporation ("RTX") are two of the leading suppliers in the worldwide market for trimmable horizontal stabilizer actuators ("THSAs") for large aircraft and are significant direct competitors. Safran's proposed acquisition of RTX's business related to THSAs threatens to substantially lessen competition in violation of Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed transaction should, therefore, be enjoined.

I. Nature of the Action

1. Pursuant to an asset purchase agreement dated July 20, 2023, Safran proposes to acquire certain assets from RTX's Collins Aerospace business comprising Collins Aerospace's flight control and actuation business, which produces THSAs for large aircraft. The transaction is valued at approximately \$1.8 billion.

2. THSAs help an aircraft maintain the proper altitude during flight and are critical to the safe operation of the aircraft. The proposed acquisition would eliminate competition between Safran and RTX in the market for THSAs for large aircraft.

3. As a result, the proposed acquisition likely would substantially lessen competition in the worldwide market for the development,

manufacture, and sale of THSAs for large aircraft in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

II. The Defendants

4. Safran S.A. is incorporated in France and has its headquarters in Paris, France. Safran produces a wide range of products for the aerospace industry and other industries, including THSAs for large aircraft. Safran USA, Inc. is a US-based subsidiary of Safran S.A., headquartered in Alexandria, Virginia. In 2024, Safran had revenues of approximately €27 billion.

5. RTX is incorporated in Delaware and is headquartered in Arlington, Virginia. RTX is a major provider of aerospace and defense electronics systems. RTX produces, among other products, THSAs for large aircraft. In 2024, RTX had revenues of approximately \$80 billion.

III. Prior Divestiture in UTC-Rockwell Collins

6. On October 1, 2018, the Antitrust Division entered a consent decree requiring United Technologies Corporation ("UTC") to divest two businesses critical to the safe operation of aircraft to resolve competitive concerns raised by UTC's acquisition of Rockwell Collins, Inc. ("Rockwell Collins"). One of the divestiture businesses identified in the decree was Rockwell Collins's THSA business. Because of the safety critical nature of THSAs, it was imperative that the divestiture buyer have an established presence in the aerospace industry with well-established customer relationships. Ultimately, the Antitrust Division approved Safran as the divestiture buyer and since that time Safran has operated the divested business as a competitor in the market for THSAs.

7. In April of 2020, following UTC's acquisition of Rockwell Collins, UTC merged with Raytheon Company, forming the company now branded as RTX. Safran's proposed acquisition of RTX would recombine the THSA assets that were divested to resolve the Division's concerns with the UTC-Rockwell Collins transaction.

IV. Jurisdiction and Venue

8. The United States brings this action under Section 15 of the Clayton Act, 15 U.S.C. 25, as amended, to prevent and restrain Defendants from violating Section 7 of the Clayton Act, 15 U.S.C. 18.

9. Defendants develop, manufacture, and sell THSAs for large aircraft in the flow of interstate commerce. Defendants' activities in the development, manufacture, and sale of

these products substantially affect interstate commerce. This Court has subject matter jurisdiction over this action pursuant to Section 15 of the Clayton Act, 15 U.S.C. 25, and 28 U.S.C. 1331, 1337(a), and 1345.

10. Defendants have consented to venue and personal jurisdiction in this judicial district. Venue is therefore proper in this district under Section 12 of the Clayton Act, 15 U.S.C. 22 and 28 U.S.C. 1391(b) and (c).

V. Trimmable Horizontal Stabilizer Actuators for Large Aircraft

A. Background

11. Actuators are responsible for the proper positions of an aircraft by manipulating the "control surfaces" on its wings and tail section. A THSA is a type of actuator and helps an aircraft maintain the proper altitude during flight by adjusting ("trimming") the angle of the horizontal stabilizer, the control surface of the aircraft's tail responsible for aircraft pitch. This control surface is critical to the safety and performance of the aircraft, as a loss of control could cause the aircraft to crash. The stabilizer encounters significant aerodynamic loads for extended periods of time, and the THSA must be capable of handling these loads. THSAs thus tend to be the largest and most technically demanding actuators on an aircraft.

12. THSAs vary in size, complexity, and cost based on the size and type of aircraft on which they are used. Because large aircraft encounter significantly higher aerodynamic loads than smaller aircraft, THSAs for large aircraft are considerably larger, more complex, and more expensive than those used on smaller aircraft. Large aircraft primarily include commercial aircraft that seat at least six passengers abreast (such as the Airbus A320 and A350 and the Boeing 737, 787 and 777x) and military transport aircraft, but exclude regional aircraft, business jets, and tactical military aircraft.

13. THSAs can also vary in the type of power source used to effect actuation. Actuation can be effected using an electric or hydraulic source of control. Typically, an aircraft uses only one type so that all actuation on the aircraft, including THSAs, is controlled by either electric or hydraulic means. At the design phase, large aircraft manufacturers can choose either type of power source to control actuation. Once a plane is designed, manufacturers are unable to switch between electric or hydraulic actuation components, including THSAs, due in part to the

certification required for these components.

B. Relevant Markets

1. Product Market

14. THSAs for large aircraft do not have technical substitutes. Large aircraft manufacturers cannot switch to THSAs for smaller aircraft, or actuators for other aircraft control surfaces, because those products cannot adequately control the lift and manage the load generated by the horizontal stabilizer of a large aircraft. A small but significant increase in the price or worsening of terms of THSAs for large aircraft would not cause aircraft manufacturers to substitute THSAs designed for smaller aircraft or actuators for other control surfaces in volumes sufficient to make such a price increase unprofitable. Accordingly, THSAs for large aircraft are a line of commerce and a relevant product market within the meaning of Section 7 of the Clayton Act, 15 U.S.C. 18.

2. Geographic Market

15. The relevant geographic market within the meaning of Section 7 of the Clayton Act, 15 U.S.C. 18 is worldwide. THSAs for large aircraft are marketed internationally and may be sourced from suppliers globally because transportation costs are a small proportion of the cost of the product and thus are not a major factor in supplier selection.

C. Anticompetitive Effects of the Proposed Acquisition

16. Safran and RTX are two of the leading suppliers in the worldwide market for the development, manufacture, and sale of THSAs for large aircraft. Safran and RTX have respectively won two of the most significant recent contract awards for THSAs for large aircraft: the Boeing 777X and the Airbus A350. Boeing and Airbus are the world's largest manufacturers of passenger aircraft, and these aircraft represent two of only three THSA awards by these manufacturers in this century.

17. Other producers of THSAs tend to concentrate on THSAs for smaller aircraft, such as business jets or regional aircraft, or to focus on products for other aircraft control surfaces.

18. Safran and RTX view each other as a significant competitive threat for the development, manufacture, and sale of THSAs worldwide for large aircraft. The two companies are among the few that have demonstrated expertise in designing and producing THSAs for large aircraft. Each firm considers the

other company's offering when planning bids.

19. Customers have benefitted from the competition between Safran and RTX for the development, manufacture, and sale of THSAs worldwide for large aircraft. Competition between two of the leading suppliers of a product results in more favorable contractual terms, more innovative products, and shorter delivery times. The combination of Safran and certain assets from RTX's Collins Aerospace business would eliminate this competition and its future benefits to customers. Post-acquisition, Safran likely would have the incentive and the ability to increase prices profitably and offer less favorable contractual terms.

20. Safran and RTX also invest significantly to remain leading suppliers for the development, manufacture, and sale of THSAs worldwide for large aircraft, and aircraft manufacturers expect them to remain leading suppliers of new products in the future. The combination of Safran and certain assets from RTX's Collins Aerospace business would likely eliminate this competition, depriving large aircraft customers of the benefit of future innovation and product development.

21. The proposed acquisition, therefore, likely would substantially lessen competition for the development, manufacture, and sale of THSAs worldwide for large aircraft in violation of Section 7 of the Clayton Act.

D. Difficulty of Entry

22. Sufficient, timely entry of additional competitors into the market for THSAs for large aircraft is unlikely to prevent the harm to competition that is likely to result if the proposed transaction is consummated.

23. Designing and developing a THSA for large aircraft is technically difficult. Even manufacturers of THSAs for smaller aircraft face significant technical hurdles in designing and developing THSAs for large aircraft. As aerodynamic loads are a major design consideration for THSAs, and such loads are tightly correlated with the size of the aircraft, THSAs for large aircraft present more demanding technical challenges than those for smaller aircraft.

24. Opportunities to enter are limited. Because certification of a THSA is expensive and time-consuming, once a THSA is certified for a particular aircraft type, it is rarely replaced in the aftermarket by a different THSA. Accordingly, competition between suppliers of THSAs generally only occurs when an aircraft manufacturer is designing a new aircraft or an upgraded

version of an existing aircraft, which are infrequent occurrences because development costs for such aircraft can be tens of billions of dollars. As a result, several years usually pass between contract awards for THSAs for a new aircraft design.

25. Potential entrants into the production of THSAs for large aircraft face several additional obstacles. First, manufacturers of large aircraft are more likely to purchase THSAs from those firms already supplying THSAs for other large aircraft. The important connection between THSAs and aircraft safety drives aircraft manufacturers toward suppliers experienced with production of THSAs of the relevant type and size. While some companies may have demonstrated experience in THSAs for smaller aircraft, such experience is not considered by customers to be as relevant as experience in THSAs for large aircraft. A new entrant would face significant costs and time to be considered a potential alternative to the existing suppliers.

26. Substantial time and significant financial investment would be required for a company to design and develop a THSA for large aircraft. Even companies that already make other types of THSAs would require years of effort and an investment of many millions of dollars to develop a product that is competitive with those offered by existing large aircraft THSA suppliers.

27. As a result of these barriers, entry into the market for THSAs for large aircraft would not be timely, likely, or sufficient to defeat the substantial lessening of competition that would likely result from Safran's acquisition of certain assets from RTX's Collins Aerospace business.

VI. Violations Alleged

28. Safran's acquisition of certain assets from RTX's Collins Aerospace business likely would lessen competition substantially in the development, manufacture, and sale of THSAs for large aircraft, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

29. Unless enjoined, the proposed acquisition likely would have the following anticompetitive effects relating to THSAs for large aircraft, among others:

(a) actual and potential competition between Safran and RTX would be eliminated;

(b) competition likely would be substantially lessened; and

(c) prices would likely increase, contractual terms likely would be less favorable to the customers, quality

would likely be reduced, and innovation likely would decrease.

VII. Request for Relief

30. The United States requests that this Court:

(a) adjudge and decree that Safran's acquisition of certain assets from RTX's Collins Aerospace business would be unlawful and violate Section 7 of the Clayton Act, 15 U.S.C. 18;

(b) preliminarily and permanently enjoin and restrain Defendants and all persons acting on their behalf from consummating the proposed acquisition of certain assets from RTX's Collins Aerospace business by Safran, or from entering into or carrying out any other contract, agreement, plan, or understanding, the effect of which would be to combine Safran with certain assets from RTX's Collins Aerospace business;

(c) award the United States its costs for this action; and

(d) award the United States such other and further relief as the Court deems just and proper.

Dated: June 17, 2025.

Respectfully submitted,

For Plaintiff United States of America:

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*Lead Attorney To Be Noticed

United States District Court for the District Of Columbia

UNITED STATES OF AMERICA, Plaintiff,
v. Safran, S.A., Safran USA Inc., and RTX Corporation, Defendants.

No. 1:25-cv-01897-CRC

Judge: Christopher R. Cooper

Proposed Final Judgment

Whereas, Plaintiff, United States of America, filed its Complaint on June 17, 2025;

And Whereas, the United States and Defendants, Safran S.A., Safran USA Inc., and RTX Corporation, have consented to entry of this Final Judgment without the taking of testimony, without trial or adjudication of any issue of fact or law, and without

this Final Judgment constituting any evidence against or admission by any party relating to any issue of fact or law;

And Whereas, Defendant Safran agrees to make a divestiture to remedy the loss of competition alleged in the Complaint;

And Whereas, Defendants represent that the divestiture and other relief required by this Final Judgment can and will be made and that Defendants will not later raise a claim of hardship or difficulty as grounds for asking the Court to modify any provision of this Final Judgment;

Now Therefore, *It Is Ordered, Adjudged, And Decreed:*

I. Jurisdiction

The Court has jurisdiction over the subject matter of, and each of the parties to, this action. The Complaint states a claim upon which relief may be granted against Defendants under Section 7 of the Clayton Act (15 U.S.C. 18).

II. Definitions

As used in this Final Judgment:

A. "Safran" means Defendant Safran S.A., a French corporation with its headquarters in Paris, France, its successors and assigns, and its subsidiaries, including Defendant Safran USA Inc., divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

B. "RTX" means Defendant RTX Corporation, a Delaware corporation with its headquarters in Arlington, Virginia, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

C. "Woodward" means Woodward, Inc., a Delaware corporation with its headquarters in Fort Collins, Colorado, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

D. "Acquirer" means Woodward.

E. "Divestiture Business" means (1) Safran's North American actuation business, including the entirety of the business activities and assets engaged in the development, manufacture, and sale of trimmable horizontal stabilizer actuators ("THSAs"), secondary flight control actuation products and nose-wheel steering gearboxes; and (2) Safran Electronics & Defense, Canada Inc. ("SEDC"), Safran's Canada-based electronic control units business.

F. "Divestiture Assets" means all of Defendant Safran's rights, titles, and interests in and to all property and

assets related to the Divestiture Business, tangible and intangible, wherever located, relating to or used in connection with the Divestiture Business, including:

1. the long-term leases for the facilities located at 2000 and 2020 Fisher Dr., Peterborough, ON K9J 6X6, Canada;

2. the Transitional Safran Brands License;

3. all other real property, including fee simple interests, real property leasehold interests and renewal rights thereto, improvements to real property, and options to purchase any adjoining or other property, together with all buildings, facilities, and other structures;

4. all tangible personal property, including fixed assets, machinery and manufacturing equipment, tools, vehicles, inventory, materials, office equipment and furniture, computer hardware, and supplies;

5. all contracts, contractual rights, and customer relationships (including contracts for the supply of THSAs to Airbus, S.E), and all other agreements, commitments, and understandings, including supply agreements, teaming agreements, and leases, and all outstanding offers or solicitations to enter into a similar arrangement;

6. all licenses, permits, certifications, approvals, consents, registrations, waivers, and authorizations, including those issued or granted by any governmental organization, and all pending applications or renewals;

7. all records and data, including (a) customer lists, accounts, sales, and credits records, (b) production, repair, maintenance, and performance records, (c) manuals and technical information Defendant Safran provides to its own employees, customers, suppliers, agents, or licensees, (d) records and research data concerning historic and current research and development activities, including designs of experiments and the results of successful and unsuccessful designs and experiments, and (e) drawings, blueprints, and designs;

8. all intellectual property owned, licensed, or sublicensed, either as licensor or licensee, including (a) patents, patent applications, and inventions and discoveries that may be patentable, (b) registered and unregistered copyrights and copyright applications, and (c) registered and unregistered trademarks, trade dress, service marks, trade names, and trademark applications; and

9. all other intangible property, including (a) commercial names and d/b/a names, (b) technical information, (c)

computer software and related documentation, know-how, trade secrets, design protocols, specifications for materials, specifications for parts, specifications for devices, safety procedures (e.g., for the handling of materials and substances), quality assurance and control procedures, (d) design tools and simulation capabilities, and (e) rights in internet websites and internet domain names.

Provided, however, that the assets specified in Paragraphs II.F.1–9 above do not include the Excluded Assets.

G. “Divestiture Date” means the date on which the Divestiture Assets are divested to Acquirer pursuant to this Final Judgment.

H. “Excluded Assets” means (1) the interests in the facilities located at Av. Sierra San Agustín 2498, Col el Porvenir, Parque Industrial Progreso, and 21185 Mexicali, B.C., Mexico and 1833 Alton Parkway, Irvine, California, United States; (2) any intellectual property associated with the brand names Safran and SEDA; and (3) the contracts to supply: (i) Virgin Galactic with the mechanical portion of an electromechanical THSA actuator (on a build to print basis), (ii) the signal interface unit for user (“SIFU”) remote data concentrator for Archer Aviation, Inc., (iii) the French legacy THSA activity consisting of original equipment THSAs produced at Safran’s facilities in Mantes, Fougères, Montluçon, and Auxerre, France, for the Embraer KC–390 Millennium, the Bombardier CL650, the Pilatus PC–24 and the Piaggio P.180; (iv) the maintenance, repair, and operation services and related spare parts for the Mitsubishi Heavy Industries (MHI) CRJ family; and (v) Bell with actuation products unrelated to THSAs for helicopters.

I. “Including” means including, but not limited to.

J. “Regulatory Approvals” means (1) any approvals or clearances from the Committee on Foreign Investment in the United States (“CFIUS”) or under antitrust or competition laws that are required for the Transaction to proceed; and (2) any approvals or clearances under antitrust or competition laws that are required for Acquirer’s acquisition of the Divestiture Assets to proceed.

K. “Relevant Personnel” means (1) all full-time, part-time, or contract employees, wherever located, whose job responsibilities relate in any way to the Divestiture Business at any time between June 14, 2023, and the Divestiture Date and (2) the employees in the positions listed in Schedule A. The United States, in its sole discretion, will resolve any disagreement relating to

which employees are Relevant Personnel.

L. “Transaction” means the proposed acquisition of part of Collins Aerospace flight control and actuation business from RTX by Safran.

M. “Transitional Safran Brands License” means a non-exclusive, non-transferable, non-sublicensable, fully paid-up, worldwide license to use the marks “Safran” and “SEDA” in connection with the products and services provided under the agreements described in Section IV.K for a time period equal to the duration of those agreements and any extensions approved by the United States and a non-exclusive, non-transferable, non-sublicensable, fully paid-up, worldwide license to use the name “SEDC” for 180 days from the Divestiture Date.

N.

III. Applicability

A. This Final Judgment applies to Safran and RTX, as defined above, and all other persons in active concert or participation with any Defendant who receive actual notice of this Final Judgment.

B. If, prior to complying with Section IV of this Final Judgment, Defendants sell or otherwise dispose of all or substantially all of their assets or of business units that include the Divestiture Assets, Defendants must require any purchaser to be bound by the provisions of this Final Judgment. Defendants need not obtain such an agreement from Acquirer.

IV. Divestiture

A. Defendants are ordered and directed, within 90 calendar days after the Court’s entry of the Asset Preservation and Hold Separate Stipulation and Order in this matter or within 90 calendar days after Regulatory Approvals are received, whichever is later, to divest the Divestiture Assets in a manner consistent with this Final Judgment to Woodward. The United States, in its sole discretion, may agree to one or more extensions of this time period and will notify the Court of any extension.

B. For all contracts, agreements, and customer or supplier relationships (or portions of such contracts, agreements, and customer or supplier relationships) included in the Divestiture Assets, Defendant Safran must assign or otherwise transfer all contracts, agreements, and customer or supplier relationships, including contracts for the supply of THSAs to Airbus, SE, to Acquirer; *provided, however,* that for any contract or agreement that requires the consent of another party to assign or

otherwise transfer, Defendant Safran must use best efforts to accomplish the assignment or transfer. Defendants must not interfere with any negotiations between Acquirer and a contracting party.

C. Defendants must use best efforts to divest the Divestiture Assets as expeditiously as possible. Defendants must take no action that would jeopardize the completion of the divestiture ordered by the Court, including any action to impede the permitting, operation, or divestiture of the Divestiture Assets.

D. Unless the United States otherwise consents in writing, divestiture pursuant to this Final Judgment must include the entire Divestiture Assets and must be accomplished in such a way as to satisfy the United States, in its sole discretion, that the Divestiture Assets can and will be used by Acquirer as part of a viable, ongoing business for the development, manufacture, and sale of THSAs and that the divestiture to Acquirer will remedy the competitive harm alleged in the Complaint.

E. The divestiture must be made to an Acquirer that, in the United States’ sole judgment, has the intent and capability, including the necessary managerial, operational, technical, and financial capability, to compete effectively in the development, manufacture, and sale of THSAs.

F. The divestiture must be accomplished in a manner that satisfies the United States, in its sole discretion, that none of the terms of any agreement between Acquirer and Defendants give Defendants the ability unreasonably to raise Acquirer’s costs, to lower Acquirer’s efficiency, or otherwise interfere in the ability of Acquirer to compete effectively in the development, manufacture, and sale of THSAs.

G. Defendant Safran must provide Acquirer with (1) access to make inspections of the Divestiture Assets; (2) access to all environmental, zoning, and other permitting documents and information relating to the Divestiture Assets; and (3) access to all financial, operational, or other documents and information relating to the Divestiture Assets that would customarily be provided as part of a due diligence process. Defendants also must disclose all encumbrances on any part of the Divestiture Assets, including on intangible property.

H. Defendant Safran must cooperate with and assist Acquirer in identifying and, at the option of Acquirer, hiring all Relevant Personnel, including:

1. Within 10 business days following the filing of the Complaint in this matter, Defendant Safran must identify

all Relevant Personnel to Acquirer and the United States, including by providing organization charts covering all Relevant Personnel.

2. Within 10 business days following receipt of a request by Acquirer, the United States, or the monitor, Defendant Safran must provide to Acquirer, the United States, and the monitor additional information relating to Relevant Personnel, including name, job title, reporting relationships, past experience, responsibilities, training and educational histories, relevant certifications, and job performance evaluations. Defendant Safran must also provide to Acquirer, the United States, and the monitor information relating to current and accrued compensation and benefits of Relevant Personnel, including most recent bonuses paid, aggregate annual compensation, current target or guaranteed bonus, if any, any retention agreement or incentives, and any other payments due, compensation or benefits accrued, or promises made to the Relevant Personnel. If Defendant Safran is barred by any applicable law from providing any of this information, Defendant Safran must provide, within 10 business days following receipt of the request, the requested information to the full extent permitted by law and also must provide a written explanation of Defendant Safran's inability to provide the remaining information, including specifically identifying the provisions of the applicable laws.

3. At the request of Acquirer, Defendant Safran must promptly make Relevant Personnel available for private interviews with Acquirer during normal business hours at a mutually agreeable location.

4. Defendants must not interfere with any effort by Acquirer to employ any Relevant Personnel. Interference includes offering to increase the compensation or improve the benefits of Relevant Personnel unless (a) the offer is part of a company-wide increase in compensation or improvement in benefits that was announced prior to June 14, 2023, or (b) the offer is approved by the United States in its sole discretion. Defendants' obligations under this Paragraph IV.H.4. will expire 180 calendar days after the Divestiture Date.

5. For Relevant Personnel who elect employment with Acquirer within 180 calendar days of the Divestiture Date, Defendant Safran must waive all non-compete and non-disclosure agreements; vest and pay to the Relevant Personnel (or to Acquirer for payment to the employee) on a prorated basis any bonuses, incentives, other salary, benefits or other compensation fully or

partially accrued at the time of the transfer of the employee to Acquirer; vest any unvested pension and other equity rights; and provide all other benefits that those Relevant Personnel otherwise would have been provided had the Relevant Personnel continued employment with Defendant Safran, including any retention bonuses or payments. Defendant Safran may maintain reasonable restrictions on disclosure by Relevant Personnel of Defendant Safran's proprietary non-public information that is unrelated to the Divestiture Assets and not otherwise required to be disclosed by this Final Judgment.

6. For a period of 12 months from the Divestiture Date, Defendant Safran may not solicit to rehire Relevant Personnel who were hired by Acquirer within 180 calendar days of the Divestiture Date unless (a) an individual is terminated or laid off by Acquirer or (b) Acquirer agrees in writing that Defendant Safran may solicit to re-hire that individual. Nothing in this Paragraph IV.H.6. prohibits Defendants from advertising employment openings using general solicitations or advertisements and re-hiring Relevant Personnel who apply for an employment opening through a general solicitation or advertisement.

I. Defendant Safran must warrant to Acquirer that (1) the Divestiture Assets will be operational and without material defect on the date of their transfer to Acquirer; (2) there are no material defects in the environmental, zoning, or other permits relating to the operation of the Divestiture Assets; and (3) Defendant Safran has disclosed all encumbrances on any part of the Divestiture Assets, including on intangible property. Following the sale of the Divestiture Assets, Defendants must not undertake, directly or indirectly, challenges to the environmental, zoning, or other permits relating to the operation of the Divestiture Assets.

J. Defendant Safran must use best efforts to assist Acquirer to obtain all necessary licenses, registrations, and permits to operate the Divestiture Business. Until Acquirer obtains the necessary licenses, registrations, and permits, Defendant Safran must provide Acquirer with the benefit of Defendant Safran's licenses, registrations, and permits to the full extent permissible by law.

K. At the option of Acquirer, subject to approval by the United States in its sole discretion, on or before the Divestiture Date, Defendant Safran must enter into a contract or contracts for the operation of the portion of the Divestiture Assets located at Av. Sierra

San Agustín 2498, Col el Porvenir, Parque Industrial Progreso, and 21185 Mexicali, B.C., Mexico, facilities, sufficient to meet Acquirer's needs, as determined by Acquirer, for a period of up to 24 months, on terms and conditions reasonably related to market conditions for such asset operation. At the option of Acquirer, subject to approval by the United States in its sole discretion, Defendant Safran must enter into one or more extensions of any such contracts for a total of up to an additional 12 months, on terms and conditions reasonably related to market conditions for such asset operation. Any amendment to or modification of any provision of any such contract or extension must first be approved by the United States, in its sole discretion. If Acquirer seeks an extension of the term of any such contract, Defendant Safran must notify the United States in writing at least 30 days prior to the date the contract expires. Acquirer may terminate such a contract (including an extension), or any portion of such a contract (including an extension), without cost or penalty upon 60 calendar days' written notice. The employees of Defendant Safran tasked with operation of the Divestiture Assets located in Mexicali must not share any competitively sensitive information of Acquirer with any employee of Defendants other than those tasked with providing operation services.

L. At the option of Acquirer, and subject to approval by the United States in its sole discretion, on or before the Divestiture Date, Defendant Safran must enter into a contract to provide transition services for back office, human resources, accounting, employee health and safety, and information technology services and support for a period of up to 24 months, on terms and conditions reasonably related to market conditions for the provision of the transition services. At the option of Acquirer, subject to approval by the United States in its sole discretion, Defendant Safran must enter into one or more extensions of any contracts to provide transition services for a total of up to an additional 12 months, on terms and conditions reasonably related to market conditions for the provision of the transition services. Any amendment to or modification of any provision of a contract or extension to provide transition services must first be approved by the United States, in its sole discretion. If Acquirer seeks an extension of the term of any contract for transition services, Defendants must notify the United States in writing at least 30 calendar days prior to the date

the contract expires. Acquirer may terminate a contract (including an extension) for transition services, or any portion of a contract (including an extension) for transition services, without cost or penalty at any time upon 30 calendar days' written notice. The employees of Defendant Safran tasked with providing transition services must not share any competitively sensitive information of Acquirer with any other employee of Defendants, other than those tasked with providing transition services.

M. At the option of Acquirer, and subject to approval by the United States in its sole discretion, on or before the Divestiture Date, Defendants must enter into a lease or assignment of a lease for Suite 3, Section 1 on the first floor of 1733 Alton Parkway, Irvine, California 92614 for a period of up to 12 months, on terms and conditions reasonably related to market conditions for such leases. At the option of Acquirer, subject to approval by the United States in its sole discretion, Defendants must enter into one or more extensions of any lease for a total of up to an additional 12 months, on terms and conditions reasonably related to market conditions for such leases. Any amendment to or modification of any provision of a lease or extension must first be approved by the United States, in its sole discretion. If Acquirer seeks an extension of the term of any lease, Defendants must notify the United States in writing at least 30 calendar days prior to the date the lease expires. Acquirer may terminate a lease (including an extension), or any portion of a lease (including an extension), without cost or penalty at any time upon 30 calendar days' written notice.

N. If any term of an agreement between Defendants and Acquirer, including an agreement to effectuate the divestiture required by this Final Judgment, varies from a term of this Final Judgment, to the extent that Defendants cannot fully comply with both, this Final Judgment determines Defendants' obligations.

V. Financing

Defendants may not finance all or any part of Acquirer's purchase of all or part of the Divestiture Assets.

VI. Asset Preservation and Hold Separate

Defendants must take all steps necessary to comply with the Asset Preservation and Hold Separate Stipulation and Order entered by the Court.

VII. Affidavits

A. Within 20 calendar days of the filing of the Complaint in this matter, and every 30 calendar days thereafter until the divestiture required by this Final Judgment has been completed, each Defendant must deliver to the United States an affidavit, signed by each Defendant's Chief Financial Officer and General Counsel, describing in reasonable detail the fact and manner of that Defendant's compliance with this Final Judgment. The United States, in its sole discretion, may approve different signatories for the affidavits.

B. Defendants must keep all records of any efforts made to divest the Divestiture Assets until one year after the Divestiture Date.

C. Within 20 calendar days of the filing of the Complaint in this matter, Defendants must deliver to the United States an affidavit signed by Defendants' Chief Financial Officer and General Counsel that describes in reasonable detail all actions that Defendant Safran has taken and all steps that Defendants have implemented on an ongoing basis to comply with Section VI of this Final Judgment. The United States, in its sole discretion, may approve different signatories for the affidavits.

D. If a Defendant makes any changes to actions and steps described in affidavits provided pursuant to Paragraph VII.C., the Defendant must, within 15 calendar days after any change is implemented, deliver to the United States an affidavit describing those changes.

E. Defendants must keep all records of any efforts made to comply with Section VI until one year after the Divestiture Date.

VIII. Appointment of Monitor

A. Upon application of the United States in its sole discretion, which Defendants may not oppose, the Court will appoint a monitor selected by the United States and approved by the Court. Defendants may propose candidates for the monitor appointment to the United States. Once approved, the court-appointed monitor should be considered by the United States and Defendants to be an arm and representative of the Court.

B. The monitor will have the power and authority to monitor Defendants' compliance with the terms of this Final Judgment and the Asset Preservation and Hold Separate Stipulation and Order entered by the Court and will have other powers as the Court deems appropriate. The monitor will have no responsibility or obligation for operation of the Divestiture Assets.

C. The monitor must investigate and report on Defendants' compliance with this Final Judgment and the Asset Preservation and Hold Separate Stipulation and Order, including Paragraphs IV.H, IV.K., IV.L, IV.M. and Section X. The monitor must provide periodic reports to the United States setting forth Defendants' efforts to comply with their obligations under this Final Judgment and under the Asset Preservation and Hold Separate Stipulation and Order. The United States, in its sole discretion, will set the frequency of the monitor's reports.

D. The monitor will have the authority to take such steps as, in the monitor's discretion and the United States' view, may be necessary to accomplish the monitor's responsibilities. The monitor may seek information from Defendants' personnel, including in-house counsel, compliance personnel, and internal auditors. Defendants must establish a policy, annually communicated to all employees, that employees may disclose any information to the monitor without reprisal for such disclosure. Defendants must not retaliate against any employee or third party for disclosing information to the monitor.

E. Defendants may not object to actions taken by the monitor in fulfillment of the monitor's responsibilities under any Order of the Court on any ground other than malfeasance by the monitor. Disagreements between the monitor and Defendants related to the scope of the monitor's responsibilities do not constitute malfeasance. Objections by Defendants must be conveyed in writing to the United States and the monitor within 10 calendar days of the monitor's action that gives rise to Defendants' objection or the objection is waived.

F. The monitor will serve at the cost and expense of Defendant Safran pursuant to a written agreement, on terms and conditions, including confidentiality requirements and conflict of interest certifications, approved by the United States in its sole discretion. If the monitor and Defendant Safran are unable to reach such a written agreement within 14 calendar days of the Court's appointment of the monitor, or if the United States, in its sole discretion, declines to approve the proposed written agreement, the United States, in its sole discretion, may take appropriate action, including making a recommendation to the Court, which may set the terms and conditions for the monitor's work, including the monitor's compensation.

G. The monitor may hire, at the cost and expense of Defendant Safran, any

agents and consultants, including investment bankers, attorneys, and accountants, that are reasonably necessary in the monitor's judgment to assist with the monitor's duties. These agents or consultants will be directed by and solely accountable to the monitor and will serve on terms and conditions, including confidentiality requirements and conflict-of-interest certifications, approved by the United States in its sole discretion. Within three business days of hiring any agents or consultants, the monitor must provide written notice of the hiring and the rate of compensation to Defendant Safran and the United States. The compensation of the monitor and agents or consultants retained by the monitor must be on reasonable and customary terms commensurate with the individuals' experience and responsibilities. The monitor must account for all costs and expenses incurred.

H. Defendant Safran's failure to promptly pay the monitor's invoices and accounted-for costs and expenses, including for agents and consultants, will constitute a violation of this Final Judgment and may result in sanctions imposed by the Court. If Defendant Safran makes a timely objection in writing to the United States to any part of the monitor's invoices or accounted-for costs and expenses, Defendant Safran must establish an escrow account into which Defendant Safran must pay the disputed amount until the dispute is resolved.

I. Defendants must use best efforts to cooperate fully with the monitor and to assist the monitor to monitor Defendants' compliance with their obligations under this Final Judgment and the Asset Preservation and Hold Separate Stipulation and Order. Subject to reasonable protection for trade secrets, other confidential research, development, or commercial information, or any applicable privileges, Defendants must provide the monitor and agents or consultants retained by the monitor with full and complete access to all personnel (current and former), agents, consultants, books, records, and facilities of the Divestiture Assets. Defendants may not take any action to interfere with or to impede accomplishment of the monitor's responsibilities.

J. The monitor may communicate *ex parte* with the Court when, in the monitor's sole discretion, the monitor believes such communication is reasonably necessary to the monitor's duties under this Final Judgment, including if Defendant Safran fails to timely pay the monitor's invoices or

accounted-for costs and expenses or if Defendants otherwise violate this Final Judgment.

K. The monitor will serve until 180 calendar days after (1) the expiration of the last contracts between Defendants and Acquirer related to the operation of any of the Divestiture Assets pursuant to Paragraph IV.K, the provision of any transition services pursuant to Paragraph IV.L, the provision of any lease pursuant to Paragraph IV.M, or any other obligations of Defendants to Acquirer, and (2) the expiration of Defendants' obligations under Section X, unless the United States, in its sole discretion, determines a different period is appropriate.

L. If the United States determines that the monitor is not acting diligently or in a reasonably cost-effective manner, or if the monitor resigns or becomes unable to accomplish the monitor's duties, the United States may recommend that the Court appoint a substitute monitor.

IX. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment or of related orders such as the Asset Preservation and Hold Separate Stipulation and Order or of determining whether this Final Judgment should be modified or vacated, upon written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, and reasonable notice to Defendants, Defendants must permit, from time to time and subject to legally recognized privileges, authorized representatives, including agents retained by the United States:

1. to have access during Defendants' office hours to inspect and copy, or at the option of the United States, to require Defendants to provide electronic copies of all books, ledgers, accounts, records, data, and documents, wherever located, in the possession, custody, or control of Defendants relating to any matters contained in this Final Judgment; and

2. to interview, either informally or on the record, Defendants' officers, employees, or agents, wherever located, who may have their individual counsel present, relating to any matters contained in this Final Judgment. The interviews must be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, Defendants must submit written reports or respond to written interrogatories, under oath if

requested, relating to any matters contained in this Final Judgment.

X. Firewalls

A. Defendant Safran must implement and maintain effective procedures to prevent Acquirer's competitively sensitive information from being shared or disclosed, by or through implementation and execution of the obligations required by this Final Judgment and any associated agreements, including agreements entered pursuant to Paragraphs IV.K, IV.L, and IV.M, by the employees of Defendant Safran tasked with (1) operating the Divestiture Assets at Av. Sierra San Agustín 2498, Col el Porvenir, Parque Industrial Progreso, and 21185 Mexicali, B.C., Mexico, facilities ("Mexicali Facilities") for Acquirer, or (2) providing transition services to Acquirer (collectively, "Firewall Employees") and any other employees of Defendants. In particular, no employee of Defendant Safran assigned to, or with any management responsibility for, the Collins Aerospace flight control and actuation business may be given, or have access to, information about the production for Acquirer at the Mexicali Facilities, including information about demand, product, sales, or price.

B. Defendant Safran must, within thirty (30) calendar days of the entry of the Asset Preservation Stipulation and Order, submit to the United States and, if one has been appointed, to the monitor, a compliance plan setting forth in detail the procedures Defendant Safran proposes to implement to effect compliance with this Section X. The United States must inform Defendant Safran within ten (10) business days of receipt whether, in its sole discretion, the United States approves or rejects Defendant Safran's compliance plan. Within ten (10) business days of receiving a notice of rejection, Defendant Safran must submit a revised compliance plan. The United States may request that the Court determine whether Defendant Safran's proposed compliance plan fulfills the requirements of this Section X.

C. At minimum, an effective compliance plan must include, for all Firewall Employees, (1) initial written notice on or before the Divestiture Date, (2) training within thirty (30) days of the Divestiture Date followed by training on a yearly basis, and (3) provision of written acknowledgment of the obligations of this Section X within thirty (30) days of the Divestiture Date and on a yearly basis thereafter. The form of all written notifications must first be reviewed by the monitor, if one

has been appointed, and approved by the United States, in its sole discretion. Defendant Safran must maintain complete records of all written notices, training, employee acknowledgments, and all other efforts made to comply with this Section X until the termination of all contracts between Defendant Safran and Acquirer related to the operation of, support of, or transition services for the Divestiture Assets or five years after the Divestiture Date, whichever is later.

XI. No Reacquisition

Defendants may not reacquire any part of or any interest in the Divestiture Assets during the term of this Final Judgment without prior authorization of the United States.

XII. Public Disclosure

A. No information or documents obtained pursuant to any provision of this Final Judgment, including reports the monitor provides to the United States pursuant to Paragraph VIII.C, may be divulged by the United States or the monitor to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party, including grand-jury proceedings, for the purpose of evaluating a proposed Acquirer or securing compliance with this Final Judgment, or as otherwise required by law.

B. In the event that the monitor receives a subpoena, court order, or other court process seeking or requiring production of information or documents obtained pursuant to any provision in this Final Judgment, including reports the monitor provides to the United States pursuant to Paragraph VIII.C, the monitor must notify the United States and Defendants immediately and prior to any disclosure, so that Defendants may address such potential disclosure and, if necessary, pursue alternative legal remedies, including if deemed appropriate by Defendants, intervention in the relevant proceedings.

C. In the event of a request by a third party, pursuant to the Freedom of Information Act, 5 U.S.C. 552, for disclosure of information obtained pursuant to any provision of this Final Judgment, the Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Defendants submitting information to the Antitrust Division should designate the confidential commercial information portions of all applicable documents and information

under 28 CFR 16.7. Designations of confidentiality expire 10 years after submission, “unless the submitter requests and provides justification for a longer designation period.” See 28 CFR 16.7(b).

D. If at the time that Defendants furnish information or documents to the United States pursuant to any provision of this Final Judgment, Defendants represent and identify in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material, “Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,” the United States must give Defendants 10 calendar days’ notice before divulging the material in any legal proceeding (other than a grand jury proceeding).

XIII. Retention of Jurisdiction

The Court retains jurisdiction to enable any party to this Final Judgment to apply to the Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XIV. Enforcement of Final Judgment

A. If any time during the five years from entry of this Final Judgment, the United States determines in its sole discretion that the Final Judgment has failed to fully redress the violations alleged in the Complaint, then the United States may re-open this proceeding to seek additional relief, including divestiture of additional assets. Such additional relief may be ordered by this Court upon a finding by a preponderance of the evidence that there is a reasonable probability that the proposed Final Judgment did not fully redress the violations alleged in the Complaint.

B. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Defendants agree that in a civil contempt action, a motion to show cause, or a similar action brought by the United States relating to an alleged violation of this Final Judgment, the United States may establish a violation of this Final Judgment and the appropriateness of a remedy therefor by a preponderance of the evidence, and Defendants waive any argument that a different standard of proof should apply.

C. This Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws and to restore the competition the United States alleges was harmed by the challenged conduct. Defendants agree that they may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

D. In an enforcement proceeding in which the Court finds that Defendants have violated this Final Judgment, the United States may apply to the Court for an extension of this Final Judgment, together with other relief that may be appropriate. In connection with a successful effort by the United States to enforce this Final Judgment against a Defendant, whether litigated or resolved before litigation, that Defendant agrees to reimburse the United States for the fees and expenses of its attorneys, as well as all other costs including experts’ fees, incurred in connection with that effort to enforce this Final Judgment, including in the investigation of the potential violation.

E. For a period of four years following the expiration of this Final Judgment, if the United States has evidence that a Defendant violated this Final Judgment before it expired, the United States may file an action against that Defendant in this Court requesting that the Court order: (1) Defendant to comply with the terms of this Final Judgment for an additional term of at least four years following the filing of the enforcement action; (2) all appropriate contempt remedies; (3) additional relief needed to ensure the Defendant complies with the terms of this Final Judgment; and (4) fees or expenses as called for by this Section XIV.

XV. Expiration of Final Judgment

Unless the Court grants an extension, this Final Judgment will expire 10 years from the date of its entry, except that after five years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestiture has been completed and continuation of this Final Judgment is no longer necessary or in the public interest.

XVI. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including by making available to the public copies of this

Final Judgment and the Competitive Impact Statement, public comments thereon, and any response to comments by the United States. Based upon the record before the Court, which includes the Competitive Impact Statement and, if applicable, any comments and response to comments filed with the

Court, entry of this Final Judgment is in the public interest.

Date: _____

Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. 16

United States District Judge

SCHEDULE A

SR. ELECTRO-MECHANICAL DESIGNER SR PROJECT ENGINEER SR PROJECT ENGINEER SR. ENGINEERING PROJECT ASSISTANT SR. ELECTRONICS TECHNICIAN PR SYSTEMS ENGINEER SENIOR ACCOUNTANT PR SYSTEMS SAFETY ENGINEER CONTRACTS MANAGER DIRECTOR OF PROGRAM MANAGEMENT (ELLINGTON) MECHANICAL ENGINEER Sr. Program Manager SR QUALITY ENGINEER DIRECTOR—ENGINEERING (ELLINGTON) SR STRESS ENGINEER SR. SUPPLIER RELATIONSHIP MANAGER SR. MECHANICAL ENGINEER SR. ELECTRONICS TECHNICIAN PR SYSTEMS ENGINEER SR ELECTRICAL ENGINEER	SafranEDA Irvine, CA. SafranEDA Irvine, CA.

United States District Court for the District of Columbia

United States of America, Plaintiff, v. Safran, S.A., Safran USA Inc., and RTX Corporation, Defendants.
1:25-cv-01897-CRC
Judge: Christopher R. Cooper

I. Competitive Impact Statement

In accordance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h) (the “APPA” or “Tunney Act”), the United States of America files this Competitive Impact Statement related to the proposed Final Judgment filed in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On July 20, 2023, Safran S.A. (“Safran”) agreed to acquire certain assets of the Collins Aerospace business from RTX Corporation (“RTX”) for approximately \$1.8 billion. The United States filed a civil antitrust Complaint on June 17, 2025, seeking to enjoin the proposed acquisition. The Complaint alleges that the likely effect of this acquisition would be to substantially lessen competition for the development, manufacture, and sale of trimmable horizontal stabilizer actuators (“THSAs”) for large aircraft in the worldwide market in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

At the same time the Complaint was filed, the United States filed a proposed Final Judgment and an Asset Preservation and Hold Separate Stipulation and Order (“Stipulation and Order”), which are designed to remedy the loss of competition alleged in the Complaint.

Under the proposed Final Judgment, which is explained more fully below, Defendant Safran is required to divest its North American actuation business, including the development, manufacture, and sale of THSAs; secondary flight control actuation products and nose-wheel steering gearboxes; and Safran’s Canada-based electronic control units business, to Woodward, Inc. (“Woodward”).

The Stipulation and Order requires Defendants to take certain steps to operate, preserve, and maintain the full economic viability, marketability, and competitiveness of the assets that must be divested pending entry of the Final Judgment by this Court. In addition, management, sales, and operations of the assets that must be divested must be held entirely separate, distinct and apart from Defendants’ other operations. The purpose of these terms in the Stipulation and Order is to ensure that competition is maintained during the pendency of the required divestiture.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment will terminate this action, except that the Court will retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

II. Description of Events Giving Rise to the Alleged Violation

A. The Defendants and the Proposed Transaction

Safran S.A. is incorporated in France and has its headquarters in Paris, France. Safran produces a wide range of products for the aerospace industry and other industries, including THSAs for large aircraft. Safran USA, Inc. is a US-based subsidiary of Safran headquartered in Alexandria, Virginia. In 2024, Safran had revenues of approximately €27 billion.

RTX is incorporated in Delaware and is headquartered in Arlington, Virginia. RTX is a major provider of aerospace and defense electronics systems. RTX produces, among other products, THSAs for large aircraft. In 2024, RTX had revenues of approximately \$80 billion.

Pursuant to an asset purchase agreement dated July 20, 2023, Defendant Safran proposes to acquire

certain assets from Defendant RTX's Collins Aerospace business. The transaction is valued at approximately \$1.8 billion.

B. Prior Divestiture in UTC-Rockwell Collins

On October 1, 2018, the Antitrust Division entered a consent decree requiring United Technologies Corporation ("UTC") to divest two businesses critical to the safe operation of aircraft to resolve competitive concerns raised by UTC's acquisition of Rockwell Collins, Inc. ("Rockwell Collins"). One of the divestiture businesses identified in the decree was Rockwell Collins's THSA business. Because of the safety critical nature of THSAs, it was imperative that the divestiture buyer have an established presence in the aerospace industry with well-established customer relationships. Ultimately, the Antitrust Division approved Safran as the divestiture buyer and, since that time, Safran has operated the divested business as a viable competitor in the market for THSAs.

In April of 2020, following UTC's acquisition of Rockwell Collins, UTC merged with Raytheon Company, forming the company now branded as RTX. The Complaint alleges that Safran's proposed acquisition of RTX would recombine the THSA assets that were divested to resolve the Division's concerns with UTC's acquisition of Rockwell Collins.

C. The Competitive Effects of the Transaction

The Complaint alleges that the transaction will result in anticompetitive effects in the market for the development, manufacture, and sale of THSAs for large aircraft.

1. Relevant Product Market

Actuators are responsible for the proper positions of an aircraft by manipulating the control surfaces on its wings and tail section. A THSA is a type of actuator and helps an aircraft maintain the proper altitude during flight by adjusting ("trimming") the angle of the horizontal stabilizer, the control surface of the aircraft's tail responsible for aircraft pitch. This control surface is critical to the safety and performance of the aircraft, as a loss of control could cause the aircraft to crash. The stabilizer encounters significant aerodynamic loads for extended periods of time, and the THSA must be capable of handling these loads. THSAs thus tend to be the largest and most technically demanding actuators on an aircraft.

THSAs vary in size, complexity, and cost based on the size and type of aircraft on which they are used. Because large aircraft encounter significantly higher aerodynamic loads than smaller aircraft, THSAs for large aircraft are considerably larger, more complex, and more expensive than those used on smaller aircraft. Large aircraft primarily include commercial aircraft that seat at least six passengers abreast (such as the Airbus A320 and A350 and the Boeing 737, 787, and 777x) and military transport aircraft, but exclude regional aircraft, business jets, and tactical military aircraft.

THSAs can also vary in the type of power source used to effect actuation. Actuation can be effected using an electric or hydraulic source of control. Typically, an aircraft uses only one type so that all actuation on the aircraft, including THSAs, is controlled by either electric or hydraulic means. At the design phase, large aircraft manufacturers can choose either type of power source to control actuation. Once a plane is designed, manufacturers are unable to switch between electric or hydraulic actuation components, including THSAs, due in part to the certification required for these components.

THSAs for large aircraft do not have technical substitutes. Large aircraft manufacturers cannot switch to THSAs for smaller aircraft, or actuators for other aircraft control surfaces, because those products cannot adequately control the lift and manage the load generated by the horizontal stabilizer of a large aircraft. A small but significant increase in the price of THSAs for large aircraft would not cause aircraft manufacturers to substitute THSAs designed for smaller aircraft or actuators for other control surfaces in volumes sufficient to make such a price increase unprofitable. Accordingly, THSAs for large aircraft are a line of commerce and a relevant product market within the meaning of Section 7 of the Clayton Act, 15 U.S.C. 18.

2. Relevant Geographic Market

The relevant geographic market within the meaning of Section 7 of the Clayton Act, 15 U.S.C. 18 is worldwide. THSAs for large aircraft are marketed internationally and may be sourced from suppliers globally because transportation costs are a small proportion of the cost of the product and, thus, are not a major factor in supplier selection.

3. Competitive Effects

Safran and RTX are two of the leading suppliers in the worldwide market for

the development, manufacture, and sale of THSAs for large aircraft. Safran and RTX have respectively won two of the most significant recent contract awards for THSAs for large aircraft: the Boeing 777X and the Airbus A350. Boeing and Airbus are the world's largest manufacturers of passenger aircraft, and these aircraft represent two of only three THSA awards by these manufacturers in this century. Other producers of THSAs tend to concentrate on THSAs for smaller aircraft, such as business jets or regional jets, or to focus on products for other aircraft control surfaces.

Safran and RTX view each other as a significant competitive threat for the development, manufacture, and sale of THSAs worldwide for large aircraft. The two companies are among the few that have demonstrated expertise in designing and producing THSAs for large aircraft. Each firm considers the other company's offering when planning bids. Customers have benefitted from the competition between Safran and RTX for the development, manufacture, and sale of THSAs worldwide for large aircraft. Competition between two of the leading suppliers of a product results in more favorable contractual terms, more innovative products, and shorter delivery times. The combination of Safran and certain assets from RTX's Collins Aerospace business would eliminate this competition and its future benefits to customers. Post-acquisition, Safran likely would have the incentive and the ability to increase prices profitably and offer less favorable contractual terms.

Safran and RTX also invest significantly to remain leading suppliers for the development, manufacture, and sale of THSAs worldwide for large aircraft, and aircraft manufacturers expect them to remain leading suppliers of new products in the future. The combination of Safran and certain assets from RTX's Collins Aerospace business would likely eliminate this competition, depriving large aircraft customers of the benefit of future innovation and product development.

The proposed acquisition, therefore, likely would substantially lessen competition for the development, manufacture, and sale of THSAs worldwide for large aircraft in violation of Section 7 of the Clayton Act.

4. Difficulty of Entry

Sufficient, timely entry of additional competitors into the market for THSAs for large aircraft is unlikely to prevent the harm to competition that is likely to result if the proposed transaction is consummated.

Designing and developing a THSA for large aircraft is technically difficult. Even manufacturers of THSAs for smaller aircraft face significant technical hurdles in designing and developing THSAs for large aircraft. As aerodynamic loads are a major design consideration for THSAs, and such loads are tightly correlated with the size of the aircraft, THSAs for large aircraft present more demanding technical challenges than those for smaller aircraft.

Opportunities to enter are limited. Because certification of a THSA is expensive and time-consuming, once a THSA is certified for a particular aircraft type, it is rarely replaced in the aftermarket by a different THSA. Accordingly, competition between suppliers of THSAs generally only occurs when an aircraft manufacturer is designing a new aircraft or an upgraded version of an existing aircraft, which are infrequent occurrences because development costs for such aircraft can be tens of billions of dollars. As a result, several years usually pass between contract awards for THSAs for a new aircraft design.

Potential entrants into the production of THSAs for large aircraft face several additional obstacles. First, manufacturers of large aircraft are more likely to purchase THSAs from those firms already supplying THSAs for other large aircraft. The important connection between THSAs and aircraft safety drives aircraft manufacturers toward suppliers experienced with production of THSAs of the relevant type and size. While some companies may have demonstrated experience in THSAs for smaller aircraft, such experience is not considered by customers to be as relevant as experience in THSAs for large aircraft. A new entrant would face significant costs and time to be considered a potential alternative to the existing suppliers.

Substantial time and significant financial investment would be required for a company to design and develop a THSA for large aircraft. Even companies that already make other types of THSAs would require years of effort and an investment of many millions of dollars to develop a product that is competitive with those offered by existing large aircraft THSA suppliers.

As a result of these barriers, entry into the market for THSAs for large aircraft would not be timely, likely, or sufficient to defeat the substantial lessening of competition that would likely result from Safran's acquisition of certain assets from RTX's Collins Aerospace business.

III. Explanation of the Proposed Final Judgment

Paragraph IV.A of the proposed Final Judgment requires Defendant Safran, within 90 days after the entry of the Stipulation and Order by the Court or within 90 days after regulatory approvals are received, to divest Safran's North American actuation business, explained in further detail below, including the development, manufacture, and sale of THSAs, secondary flight control actuation products, and nose-wheel steering gearboxes; and Safran's Canada-based electronic control units business to Woodward. Defendants must take all reasonable steps necessary to accomplish the divestiture quickly and must cooperate with the acquirer. Regulatory approvals, as defined in Paragraph II.J, include any approvals or clearances: (1) from the Committee on Foreign Investment in the United States ("CFIUS") or under antitrust or competition laws that are required for the Safran-RTX transaction to proceed; and (2) under antitrust or competition laws that are required for Woodward's acquisition to proceed.

Defendant Safran is required to divest the Divestiture Assets, which consist of all of its rights, titles, and interests in and to all property and assets related to the Divestiture Business. The Divestiture Business, defined in Paragraphs II.E, includes: (1) Safran's North American actuation business, including the development, manufacture, and sale of THSAs, secondary flight control actuation products, and nose-wheel steering gearboxes; and (2) Safran Electronics & Defense, Canada Inc., Safran's Canada-based electronic control units business.

Paragraph II.F of the proposed Final Judgment identifies nine categories of Divestiture Assets, including: (1) real property interests at specified locations used in the Divestiture Business in Peterborough, Canada; (2) a transitional Safran brands license; (3) all other real property related to the Divestiture Business; (4) all personal property, including machines, manufacturing equipment, tools, inventory, and materials; (5) all contracts, contractual rights, and customer relationships and all other agreements, commitments, and understandings, including supply agreements; (6) all licenses, permits, certifications, approvals, consents, registrations, waivers, and authorizations; (7) all records and data; (8) all intellectual property owned, licensed, or sublicensed, either as licensor or licensee; and (9) all other intangible property. These Divestiture

Assets are broadly defined to ensure a complete divestiture of all assets needed for the Divested Businesses. Any exceptions to the divestiture obligations are specified in the proposed Final Judgment.

The Divestiture Assets do not include certain specified assets, as defined in Paragraph II.H as Excluded Assets, including: (1) the interests in specified facilities located in Mexicali, Mexico and Irvine, California; (2) any intellectual property associated with the brand names "Safran" and "SEDA"; and (3) the contracts to supply (i) Virgin Galactic with the mechanical portion of an electromechanical THSA actuator (on a build to print basis); (ii) the signal interface unit for user ("SIFU") remote data concentrator for Archer Aviation, Inc.; (iii) the French legacy THSA activity consisting of original equipment THSAs produced at Safran's facilities in specified locations in France, for a limited number of specified aircraft; (iv) the maintenance, repair, and operation services and related spare parts for the Mitsubishi Heavy Industries (MHI) CRJ family; and (v) the contract to supply Bell with actuation products unrelated to THSA for helicopters.

The proposed Final Judgment contains provisions intended to facilitate the acquirer's efforts to hire certain employees. Specifically, Paragraph IV.H of the proposed Final Judgment requires Defendant Safran to identify all Relevant Personnel, including by providing the acquirer and the United States with organization charts and information relating to these employees and making them available for interviews. It also provides that Defendants must not interfere with any negotiations by the acquirer to hire these employees. In addition, for employees who elect employment with the acquirer, Defendant Safran must waive all non-compete and non-disclosure agreements, vest all unvested pension and other equity rights, provide any pay pro rata, provide all compensation and benefits that those employees have fully or partially accrued, and provide all other benefits that the employees would generally be provided had those employees continued employment with Defendant Safran, including but not limited to any retention bonuses or payments. This paragraph further provides that Defendant Safran may not solicit to rehire any of those employees who were hired by the acquirer, unless an employee is terminated or laid off by the acquirer or the acquirer agrees in writing that Defendant Safran may solicit to hire that individual. The non-

solicitation period runs for one year from the date of the divestiture.

Paragraph IV.B of the proposed Final Judgment requires Defendant Safran to transfer all contracts, agreements, and relationships to the acquirer and to make best efforts to assign, subcontract, or otherwise transfer contracts or agreements that require the consent of another party before assignment, subcontracting, or other transfer. This includes the transfer of customer contracts, such as a contract with Airbus, SE for THSAs, and supplier contracts.

The proposed Final Judgment requires Defendant Safran to provide certain transition services to maintain the viability and competitiveness of the Divestiture Business during the transition to the acquirer. Paragraph IV.L of the proposed Final Judgment requires Defendant Safran, at the acquirer's option, to enter into a transition services contract(s) for back office, billing, provisioning, human resources, accounting, employee health and safety, and information technology services and support for a period of up to 24 months. The acquirer may terminate the transition services agreement, or any portion of it, without cost or penalty at any time upon commercially reasonable notice. The paragraph further requires Defendant Safran, at the acquirer's option and subject to the United States's approval, in its sole discretion, to enter into one or more extensions of this transition services agreement for a total of up to an additional 12 months and that any amendments to or modifications of any provisions of a transition services agreement are subject to approval by the United States in its sole discretion. Paragraph IV.L also provides that employees of Defendant Safran tasked with supporting this agreement must not share any competitively sensitive information of the acquirer with any other employee of Defendants, unless such sharing is for the sole purpose of providing transition services to the acquirer.

Paragraph IV.K of the proposed Final Judgment requires Defendant Safran, at the acquirer's option, to enter into a contract for operation of the portion of the Divestiture Assets located at specified locations in Mexicali, Mexico for a period of up to 24 months. The acquirer may terminate the operation contract, or any portion of it, without cost or penalty at any time upon commercially reasonable notice. Upon the acquirer's request, the United States, in its sole discretion, may approve one or more extensions of the operation contract for up to an additional 12

months and that any amendments to or modifications of any provisions of a supply contract are subject to approval by the United States, in its sole discretion. Paragraph IV.K also provides that employees of Defendant Safran tasked with supporting this contract must not share any competitively sensitive information of the acquirer with any other employee of Defendants, unless such sharing is for the sole purpose of operation of the Divestiture Assets under this contract.

Paragraph IV.M of the proposed Final Judgment requires Defendants, at acquirer's option, to enter into a lease or assignment of a lease for a specified location in Irvine, California, for a period of up to 12 months. The acquirer may terminate the lease, or any portion of it, without cost or penalty at any time upon commercially reasonable notice. The paragraph further provides that Defendants, at the acquirer's option and subject to the approval of the United States, in its sole discretion, must enter into one or more extensions of this lease or assignment of a lease for a total of up to an additional 12 months and that any amendments to or modifications of any provisions of a lease are subject to approval by the United States, in its sole discretion.

Section VIII of the proposed Final Judgment provides that the United States may appoint a monitor who will have the power and authority to investigate and report on Defendants' compliance with the terms of the Final Judgment and the Stipulation and Order, including Paragraphs IV.H, IV.K., IV.L, IV.M. and Section X. The monitor will not have any responsibility or obligation for the operation of Defendants' businesses. The monitor will serve at Defendant Safran's expense, on such terms and conditions as the United States approves, and Defendants must assist the monitor in fulfilling his or her obligations. The monitor will provide periodic reports to the United States and will serve until 180 days after the expiration of the transition services agreements, operation agreements, and lease, and the expiration of Defendants' obligations in Section X of the proposed Final Judgment to prevent Acquirer's competitively sensitive information from being shared or disclosed by or through the implements of the obligations required by the proposed Final Judgment.

Paragraph XIV.A of the proposed Final Judgment provides that, if at any time during the five (5) year period following entry of the Final Judgment, the United States determines at its sole discretion that the Final Judgment has

failed to fully redress the violations alleged in the Complaint, then the United States may re-open the proceeding to seek additional relief, including divestiture of additional assets.

Paragraph XIV.B of the proposed Final Judgment provides that the United States retains and reserves all rights to enforce the Final Judgment, including the right to seek an order of contempt from the Court. Under the terms of this paragraph, Defendants have agreed that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of the Final Judgment, the United States may establish the violation and the appropriateness of any remedy by a preponderance of the evidence and that Defendants have waived any argument that a different standard of proof should apply. This provision aligns the standard for compliance with the Final Judgment with the standard of proof that applies to the underlying offense that the Final Judgment addresses.

Paragraph XIV.C of the proposed Final Judgment provides additional clarification regarding the interpretation of the provisions of the proposed Final Judgment. The proposed Final Judgment is intended to remedy the loss of competition the United States alleges would otherwise be harmed by the transaction. Defendants agree that they will abide by the proposed Final Judgment and that they may be held in contempt of the Court for failing to comply with any provision of the proposed Final Judgment that is stated specifically and in reasonable detail, as interpreted in light of this procompetitive purpose.

Paragraph XIV.D of the proposed Final Judgment provides that if the Court finds in an enforcement proceeding that a Defendant has violated the Final Judgment, the United States may apply to the Court for an extension of the Final Judgment, together with such other relief as may be appropriate. In addition, to compensate American taxpayers for any costs associated with investigating and enforcing violations of the Final Judgment, Paragraph XIV.D provides that, in any successful effort by the United States to enforce the Final Judgment against a Defendant, whether litigated or resolved before litigation, the Defendant must reimburse the United States for attorneys' fees, experts' fees, and other costs incurred in connection with that effort to enforce this Final Judgment, including the investigation of the potential violation.

Paragraph XIV.E of the proposed Final Judgment states that the United States may file an action against a Defendant for violating the Final Judgment for up to four years after the Final Judgment has expired or been terminated. This provision is meant to address circumstances such as when evidence that a violation of the Final Judgment occurred during the term of the Final Judgment is not discovered until after the Final Judgment has expired or been terminated or when there is not sufficient time for the United States to complete an investigation of an alleged violation until after the Final Judgment has expired or been terminated. This provision, therefore, makes clear that, for four years after the Final Judgment has expired or been terminated, the United States may still challenge a violation that occurred during the term of the Final Judgment.

Finally, Section XV of the proposed Final Judgment provides that the Final Judgment will expire ten (10) years from the date of its entry, except that after five (5) years from the date of its entry, the Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestiture has been completed and continuation of the Final Judgment is no longer necessary or in the public interest.

The relief required by the proposed Final Judgment is designed to remedy the loss of competition alleged in the Complaint by establishing an independent and economically viable competitor in the market for THSAs for large aircraft. The assets referenced above must be divested in such a way as to satisfy the United States, in its sole discretion, that the assets can and are likely to be operated by the acquirer as a viable, ongoing business that can compete effectively in the relevant market.

IV. Remedies Available to Potential Private Plaintiffs

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment neither impairs nor assists the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against Defendants.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within 60 days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or within 60 days of the first date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the U.S. Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time before the Court's entry of the Final Judgment. The comments and the response of the United States will be filed with the Court. In addition, the comments and the United States' responses will be published in the **Federal Register** unless the Court agrees that the United States instead may publish them on the U.S. Department of Justice, Antitrust Division's internet website.

Written comments should be submitted in English to: Soyoung Choe, Acting Chief, Defense, Industrials and Aerospace Section, Antitrust Division, United States Department of Justice, 450 Fifth St. NW, Suite 8700, Washington, DC 20530, ATR.DIA-Information@usdoj.gov.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

As an alternative to the proposed Final Judgment, the United States considered a full trial on the merits against Defendants. The United States could have continued the litigation and sought preliminary and permanent injunctions against Safran's acquisition of certain assets of the Collins

Aerospace business from RTX. Under the circumstances present here, however, the United States concludes that entry of the proposed Final Judgment is in the public interest insofar as it avoids the time, expense, and uncertainty of a full trial on the merits.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

Under the Clayton Act and APPA, proposed Final Judgments, or "consent decrees," in antitrust cases brought by the United States are subject to a 60-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment "is in the public interest." 15 U.S.C. 16(e)(1). In making that determination, the Court, in accordance with the statute as amended in 2004, is required to consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one as the government is entitled to "broad discretion to settle with the defendant within the reaches of the public interest." *United States v. Microsoft Corp.*, 56 F.3d 1448, 1461 (D.C. Cir. 1995); *United States v. U.S. Airways Grp., Inc.*, 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the "court's inquiry is limited" in Tunney Act settlements); *United States v. InBev N.V./S.A.*, No. 08-1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that a court's review of a proposed Final Judgment is limited and only inquires "into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanisms to enforce the final judgment are clear and manageable").

As the U.S. Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship

between the remedy secured and the specific allegations in the government's Complaint, whether the proposed Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether it may positively harm third parties. *See Microsoft*, 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the proposed Final Judgment, a court may not “make de novo determination of facts and issues.” *United States v. W. Elec. Co.*, 993 F.2d 1572, 1577 (D.C. Cir. 1993) (quotation marks omitted); *see also Microsoft*, 56 F.3d at 1460–62; *United States v. Alcoa, Inc.*, 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *United States v. Enova Corp.*, 107 F. Supp. 2d 10, 16 (D.D.C. 2000); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *3. Instead, “[t]he balancing of competing social and political interests affected by a proposed antitrust decree must be left, in the first instance, to the discretion of the Attorney General.” *W. Elec. Co.*, 993 F.2d at 1577 (quotation marks omitted). “The court should also bear in mind the flexibility of the public interest inquiry: the court’s function is not to determine whether the resulting array of rights and liabilities is the one that will best serve society, but only to confirm that the resulting settlement is within the reaches of the public interest.” *Microsoft*, 56 F.3d at 1460 (quotation marks omitted); *see also United States v. Deutsche Telekom AG*, No. 19–2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020). More demanding requirements would “have enormous practical consequences for the government’s ability to negotiate future settlements,” contrary to congressional intent. *Microsoft*, 56 F.3d at 1456. “The Tunney Act was not intended to create a disincentive to the use of the consent decree.” *Id.*

The United States’ predictions about the efficacy of the remedy are to be afforded deference by the Court. *See, e.g., Microsoft*, 56 F.3d at 1461 (recognizing courts should give “due respect to the Justice Department’s . . . view of the nature of its case”); *United States v. Iron Mountain, Inc.*, 217 F. Supp. 3d 146, 152–53 (D.D.C. 2016) (“In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.” (internal citations omitted)); *United States v. Republic Servs., Inc.*, 723 F. Supp. 2d 157, 160 (D.D.C. 2010)

(noting “the deferential review to which the government’s proposed remedy is accorded”); *United States v. Archer-Daniels-Midland Co.*, 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (“A district court must accord due respect to the government’s prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case.”). The ultimate question is whether “the remedies [obtained by the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the ‘reaches of the public interest.’” *Microsoft*, 56 F.3d at 1461 (quoting *W. Elec. Co.*, 900 F.2d at 309).

Moreover, the Court’s role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the Court to “construct [its] own hypothetical case and then evaluate the decree against that case.” *Microsoft*, 56 F.3d at 1459; *see also U.S. Airways*, 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government’s decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *20 (“[T]he ‘public interest’ is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged”). Because the “court’s authority to review the decree depends entirely on the government’s exercising its prosecutorial discretion by bringing a case in the first place,” it follows that “the court is only authorized to review the decree itself,” and not to “effectively redraft the complaint” to inquire into other matters that the United States did not pursue. *Microsoft*, 56 F.3d at 1459–60.

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using judgments proposed by the United States in antitrust enforcement, Public Law 108–237 § 221, and added the unambiguous instruction that “[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.” 15 U.S.C. 16(e)(2); *see also U.S. Airways*, 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: “[t]he court is nowhere compelled to go to trial or to

engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.” 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). “A court can make its public interest determination based on the competitive impact statement and response to public comments alone.” *U.S. Airways*, 38 F. Supp. 3d at 76 (citing *Enova Corp.*, 107 F. Supp. 2d at 17).

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: June 17, 2025.

Respectfully submitted,

For Plaintiff United States of America:

Daniel Monahan,
United States Department of Justice,
Antitrust Division, Defense, Industrials, and
Aerospace Section, 450 Fifth St. NW, Suite
8700, Washington, DC 20530, Telephone:
202–598–8774, Email: daniel.monahan@
usdoj.gov.

[FR Doc. 2025–12329 Filed 7–1–25; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

[OMB Number 1125–0007]

Agency Information Collection Activities; Proposed Collection eComments Requested; Extension and Revision of a Previously Approved Collection; Immigration Practitioner/Organization Complaint Form

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

ACTION: 60-Day notice.

SUMMARY: The Executive Office for Immigration Review (EOIR), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until September 2, 2025.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Justine Fuga, Associate General

Counsel, Office of the General Counsel, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2600, Falls Church, VA 22041, telephone: (703) 305–0265, Justine.Fuga@usdoj.gov, eoir.pra.comments@usdoj.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms

of information technology, *e.g.*, permitting electronic submission of responses.

Abstract: Any individual may file a complaint against an immigration practitioner authorized to practice before the Board of Immigration Appeals (Board) and the immigration courts of EOIR. *See* 8 CFR 1003.102. An individual filing a complaint regarding a practitioner’s behavior in proceedings before EOIR must file the complaint in writing by mail or email to EOIR’s Office of the General Counsel’s Attorney Discipline Unit (ADU) using Form EOIR–44. The completed form must state in detail certain information supporting the complaint, including the name and address of both the complainant and the practitioner, the date and nature of the alleged conduct or behavior at issue, the individuals involved, the harm to or damages incurred by the complainant, and any other relevant information. *See* 8 CFR 1003.104(a)(2). The information on this form will be used to determine whether the ADU should conduct a preliminary disciplinary inquiry, request additional information from the complainant, refer the matter to a state bar disciplinary authority or other law enforcement agency, or take no further action. EOIR has revised the Privacy Act Notice on

the form to update citations to legal authority and clarify how EOIR uses the collected information.

Overview of This Information Collection

1. *Type of Information Collection:* Extension and Revision of a previously approved collection.
2. *The Title of the Form/Collection:* Immigration Practitioner Complaint Form.
3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The agency form number is EOIR–44, and the sponsoring component is EOIR.
4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* The affected public are individuals and households. The obligation to respond is voluntary.
5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that an average of 100 respondents will complete the form annually with an average of 2 hours per response.
6. *An estimate of the total annual burden (in hours) associated with the collection:* EOIR estimates an average of 200 total annual burden hours associated with this collection.

Activity	Number of respondents	Frequency (annually)	Total annual responses	Time per response (hours)	Total annual burden (hours)
EOIR–44—individuals or households	100	1	100	2	200

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* The total estimated annual public cost is \$1,020. There are no capital or start-up costs associated with this information collection. There are no fees associated with filing the form. Most responses are printed and submitted by mail to the agency. The total annual printing cost to individuals is estimated at \$10.00 (\$0.10 per page × 1 page × 100 respondents). The total postage cost to individuals is estimated at \$1,010.00 (\$10.10 Priority Mail flat rate envelope × 100 respondents). However, the printing and postage costs may be avoided by electronically completing the form and submitting the form by email.

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and

Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: June 27, 2025.

Darwin Arceo,
Department Clearance Officer for PRA, U.S. Department of Justice.
[FR Doc. 2025–12291 Filed 7–1–25; 8:45 am]
BILLING CODE 4410–30–P

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

Cost Accounting Standards Board Meeting Agenda

AGENCY: Cost Accounting Standards Board, Office Federal Procurement Policy, Office of Management and Budget.

ACTION: Notice of agenda for closed Cost Accounting Standards Board meetings.

SUMMARY: The Office of Federal Procurement Policy (OFPP), Cost Accounting Standards Board (CAS Board) is publishing this notice to advise the public of its upcoming meetings. The meetings are closed to the public.

ADDRESSES: New Executive Office Building, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: John L. McClung, Manager, Cost Accounting Standards Board (telephone: 202–881–9758; email: john.l.mcclung2@omb.eop.gov).

SUPPLEMENTARY INFORMATION: The CAS Board is issuing this notice to inform the public of the discussion topics for a monthly meeting that was held in June and for meetings scheduled for July, August, and September 2025. The list of

agenda items for these meetings is set forth below. While CAS Board meetings are closed to the public, the Board welcomes comments and inquiries, which may be directed to the manager using the contact information provided above.

Agenda for CAS Board Meetings During the Third and Fourth Quarter, Fiscal Year 2025

1. *Statutory CAS Thresholds.* The Board will review and discuss the proposal previously transmitted to Congress during the first Trump Administration that would decouple the monetary threshold for CAS applicability from the threshold for Truth in Negotiations Act applicability, increase the basic threshold for CAS applicability, and eliminate the requirement for at least one contract at a minimum value.

2. *Regulatory CAS Thresholds.* The Board will review options and consider proposed rulemaking to increase the current regulatory threshold for full CAS coverage, which is \$50 million (48 CFR 9903.201–2), and the threshold for disclosure requirements, which is \$50 million (48 CFR 9903.202–1.) As part of those discussions, the Board will review the approach and recommendation made by the Section 809 Panel.

3. *Conformance of CAS to Generally Accepted Accounting Principles (GAAP).* 41 U.S.C. 1501(c)(2) requires the CAS Board to review and conform Cost Accounting Standards (CAS), where practicable, to GAAP. The CAS Board will review and resume deliberations on ongoing cases related to CAS 404, 408, 409, and 411 and open cases related to the three additional standards that the Board identified in its 2018 Staff Discussion Paper (84 FR 9143) on CAS–GAAP Harmonization as suitable for conformance (*i.e.*, CAS 407, 415, 416). The Board will also discuss issuance of the final rule addressing the impact of GAAP changes to operating revenue and lease accounting. The Board intends to significantly accelerate work on conformance, in furtherance of the Administration's prioritization on deregulation and reducing unnecessary transaction costs for contracting parties.

4. *Cost impact of accounting changes.* The Board will discuss the current handling of cost impact in Part 30 of the Federal Acquisition Regulation (FAR) and identify potential options that might be considered as the Federal Acquisition Regulatory Council develops a regulatory deviation to streamline FAR Part 30 in furtherance of Executive Order 14275.

5. *Application of CAS to Indefinite Delivery Vehicle (IDVs) contracts.* The

Board will review options and identify a path forward for clarifying application of CAS to IDVs in a proposed rulemaking including consideration of public comments received from the Staff Discussion Paper 85 FR 51491 (June 18, 2024).

This notice is published pursuant to 41 U.S.C. 1501(d), which requires the CAS Board to publish agendas of its meetings in the **Federal Register**.

Mathew Blum,

Acting Administrator, Office of Federal Procurement Policy, and Acting Chair, Cost Accounting Standards Board.

[FR Doc. 2025–12292 Filed 7–1–25; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Guidance on Referrals for Potential Criminal Enforcement

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice.

SUMMARY: This notice describes the NCUA's plans to address criminally liable regulatory offenses under the recent executive order on Fighting Overcriminalization in Federal Regulations.

FOR FURTHER INFORMATION CONTACT: John H. Brolin, Senior Staff Attorney, Division of Regulations and Legislation, Office of General Counsel, at 1775 Duke Street, Alexandria, VA 22314 or by telephone at (703) 518–6540.

SUPPLEMENTARY INFORMATION: On May 9, 2025, the President issued Executive Order (“E.O.”) 14294, Fighting Overcriminalization in Federal Regulations. 90 FR 20363 (published May 14, 2025). Section 7 of E.O. 14294 provides that within 45 days of the order, and in consultation with the Attorney General, each agency should publish guidance in the **Federal Register** describing its plan to address criminally liable regulatory offenses.

Consistent with that requirement, the NCUA Board advises the public that by May 9, 2026, the NCUA, in consultation with the Attorney General, will provide to the Director of the Office of Management and Budget a report containing: (1) a list of all criminal regulatory offenses¹ enforceable by the NCUA or the Department of Justice (“DOJ”); and (2) for each such criminal regulatory offense, the range of potential

criminal penalties for a violation and the applicable *mens rea* standard² for the criminal regulatory offense.

This notice also announces a general policy, subject to appropriate exceptions and to the extent consistent with law, that when the NCUA is deciding whether to refer alleged violations of criminal regulatory offenses to DOJ, officers and employees of the NCUA should consider, among other factors:

- the harm or risk of harm, pecuniary or otherwise, caused by the alleged offense;
- the potential gain to the putative defendant that could result from the offense;
- whether the putative defendant held specialized knowledge, expertise, or was licensed in an industry related to the rule or regulation at issue; and
- evidence, if any is available, of the putative defendant's general awareness of the unlawfulness of his conduct as well as his knowledge or lack thereof of the regulation at issue.

This general policy is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

By the National Credit Union Administration Board on June 26, 2025.

Melane Conyers-Ausbrooks,
Secretary of the Board.

[FR Doc. 2025–12330 Filed 7–1–25; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; National Science Foundation Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Pre-Award Information Collection.

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to renew this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

¹ “Criminal regulatory offense” means a Federal regulation that is enforceable by a criminal penalty. E.O. 14294, sec. 3(b).

² “*Mens rea*” means the state of mind that by law must be proven to convict a particular defendant of a particular crime. E.O. 14294, sec. 3(c).

DATES: Written comments on this notice must be received by September 2, 2025 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite W18200, 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:
Title of Collection: National Science Foundation (NSF) Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Pre-Award Information Collection.
OMB Control No.: 3145-0270.
Expiration Date of Approval: 11/30/2025.

Abstract: The NSF SBIR/STTR programs focus on transforming scientific discovery into products and services with commercial potential and/or societal benefit. Unlike fundamental or basic research activities that focus on scientific and engineering discoveries, the NSF SBIR/STTR programs support the creation of opportunities to move fundamental science and engineering out of the lab and into the market at scale, through startups and small businesses representing deep technology ventures.

The NSF SBIR/STTR programs request renewal clearance of this data collection that will allow the programs to collect information from a selected group of applicants—those that have been reviewed by independent experts

and that NSF Program Directors are considering recommending for funding—for the purpose of making a funding decision. This information includes, but is not exclusive to, a list of company officers and the corresponding ownership status of each company officer within the startup, whether the startup is associated or affiliated with other companies, whether there exist any relationships (personal, financial, and/or professional) between project personnel, and the locations of all the facilities where significant research will be performed for the proposed project. In addition, a list of questions pertaining to foreign influence disclosure—such as whether the applicant is affiliated with any malign foreign talent recruitment program, whether the parent company, joint venture, or subsidiary of the applicant receives funding from any foreign country of concern, and/or any financial investments made from such foreign country of concern—will be included in the questionnaire.

Such data will enable the NSF Program Directors to evaluate a given company’s business structure, ascertain the level of commitment of the Principal Investigator (PI) and co-PIs to the startup venture, identify conflicts of interests (if any), and ascertain that these applicants are not influenced by and/or affiliated with any foreign country of concern (please see https://www.sbir.gov/foreign_disclosures for the most up-to-date and completed list of these countries) as part of the due diligence process that the programs undertake to verify there are no fraudulent or inappropriate business practices prior to recommending the small business for an award.

Following standard OMB requirements, NSF will request OMB approval in advance and provide OMB

with a copy of the form containing these questions. Data collected will be used strictly for due-diligence, auditing, and/or legal purposes, and are needed for effective pre-award management, administration, and/or program monitoring. The applicants, if being considered for an award, will only be asked to submit a signed form containing their responses to the questions once for *each* NSF SBIR/STTR proposal. The data collection burden to the selected applicants will be limited to no more than 15 minutes of the respondents’ time in each instance. Summaries of the collected data are also being used to respond to queries from Congress, the Small Business Administration, the public, NSF’s external merit reviewers who serve as advisors, NSF’s Office of the Inspector General, and other pertinent stakeholders

Respondents: PIs listed on the NSF SBIR/STTR proposals.

Estimated Number of Annual Respondents: 1000.

Burden on the Public: The overall annualized cost to the respondents is estimated to be \$11,000. The following table shows the annualized estimate of costs to PIs who are generally university assistant professors. This estimated hourly rate is based on a report from the American Association of University Professors, “Annual Report on the Economic Status of the Profession, 2020–21,” *Academe*, March–April 2021, Survey Report Table 1. According to this report: https://www.aaup.org/file/AAUP_ARES_2020-21.pdf, the average salary of an assistant professor across all types of doctoral-granting institutions was \$91,408. When divided by the number of standard annual work hours (2,080), this calculates to approximately \$44 per hour.

Respondent type	Number of respondents	Burden hours per respondent	Average hourly rate	Estimated annual cost
PIs	1000	0.25	\$44	\$11,000
Total				11,000

Dated: June 30, 2025.
Suzanne H. Plimpton,
Reports Clearance Officer, National Science Foundation.
[FR Doc. 2025-12392 Filed 7-1-25; 8:45 am]
BILLING CODE 7555-01-P

NATIONAL SCIENCE FOUNDATION
Agency Information Collection
Activities: Comment Request; National Science Foundation Breakthrough Innovations Initiative Application
AGENCY: National Science Foundation.
ACTION: Notice.
SUMMARY: The National Science Foundation (NSF) is announcing plans

to renew this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing this opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by September 2, 2025 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite E6300, 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:

Title of Collection: National Science Foundation Breakthrough Innovations Initiative Application.

OMB Control No.: 3145-NEW.

Expiration Date of Approval: Not applicable.

Abstract: The U.S. National Science Foundation (NSF) Directorate for Technology, Innovation and Partnerships (TIP) is launching an effort to enable researchers, innovators, and entrepreneurs to apply unconventional approaches to create game-changing technologies and translate discoveries into tangible applications and products.

This effort will utilize a process based on the German Federal Agency for Breakthrough Innovation (SPRIND) Challenge prize model with the intention of accelerating timelines for selecting and conducting translational research, including through a significantly streamlined application form, submission portal, and selection process. The administrative burden on the applicants and selected teams will be reduced, and data will be collected to assess whether this has a positive

impact on the speed of innovation, including the time to market. Through this effort, NSF investment will help teams advance high-risk, high-reward ideas on NSF-defined topics and facilitate mentoring and technical assistance to enable teams to meet NSF-defined milestones and objectives and maximize their translational potential.

As Office of Science and Technology Policy (OSTP) Director Kratsios said in his policy speeches on April 14 and May 19, 2025: “*It is the duty of government to enable scientists to create new theories and empower engineers to put them into practice. Prizes, advanced market commitments, and other novel funding mechanisms, like fast and flexible grants, can multiply the impact of government-funded research.*” Thus, in this current effort, we are piloting a novel, fast, and flexible funding mechanism through a short application and streamlined selection process.

NSF TIP is establishing this new data collection for the application form that will allow managing program officers to collect the necessary information from applicants for the purpose of making a funding decision. This information includes, but is not exclusive to, name, job title, professional affiliation, email address and phone number of the applicant(s), along with a description (no more than 2,000 words) of the proposed idea/solution pertaining to the scientific/technical track or theme of the corresponding challenge. Specifically, the information requested would include: (1) how applicants aim to technically reach the track’s goals and milestones, (2) how their solution could be integrated into downstream processes, and (3) what preliminary work has been completed, and the technical maturity of the proposed technology. In addition, the application form would also request descriptions of

a work plan (of no more than 1000 words) detailing the schedule, cost, personnel, infrastructure, and a narrative (of no more than 500 words) outlining the knowledge and expertise of each member of the project team. Finally, the application would contain a certification section pertaining to foreign influence disclosures, such as whether the applicant is affiliated with any malign foreign talent recruitment program, and whether any of the team members receives funding from any foreign country of concern.

Data collected will be used strictly for funding decisions, due-diligence, auditing, and/or legal purposes, and are needed for effective award management, oversight, and administration. The data collection burden for the application form is estimated to be 15 to 25 hours of the respondents’ time in each instance.

Respondents: Principal Investigators (PIs) of the Breakthrough Innovations Initiative.

Estimated Number of Annual Respondents: 100.

Burden on the Public: The overall annualized cost to the respondents is estimated to be \$79,500–\$132,500. The following table shows the annualized estimate of costs to PIs who are generally university faculty. This estimated hourly rate is based on a report from the American Association of University Professors, “The Annual Report on the Economic Status of the Profession, 2022–23,” *Academe*, June 2023, Survey Report Table 1. According to this report, the average salary of an associate professor across all types of doctoral-granting institutions was \$110,945. When divided by the number of standard annual work hours (2,080), this calculates to approximately \$53 per hour.

Respondent type	Number of respondents	Burden hours per respondent	Average hourly rate	Estimated annual cost
PIs	100	15–25	\$53	\$79,500–\$132,500
Total				\$79,500–\$132,500

Dated: June 30, 2025.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2025-12375 Filed 7-1-25; 8:45 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-302; NRC-2025-0181]

Accelerated Decommissioning Partners Crystal River Unit 3, LLC; Crystal River Unit 3 Nuclear Generating Plant

AGENCY: Nuclear Regulatory Commission.

ACTION: Public meeting; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering a request from Accelerated Decommissioning Partners Crystal River Unit 3, LLC (ADP) to approve the release of land areas, under the control of the NRC power reactor license for the Crystal River Unit 3 Nuclear Generating Plant (Crystal River Unit 3, CR3),

Operating License No. DPR-72. The NRC is soliciting public comments on the requested action and invites stakeholders and interested persons to participate.

DATES: Submit comments by August 1, 2025. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date. A public meeting will be held on July 23, 2025. See Section III, "Request for Comment and Public Meeting," of this document for more information.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for: Docket ID NRC-2025-0181. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301-415-1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Office of Administration, Mail Stop: TWFN-7A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Chris Allen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6877; email: William.Allen@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2025-0181 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-0181.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at

<https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. The ADP's request is available in ADAMS under Package Accession No. ML25041A177.

- **NRC'S PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC-2025-0181 in your comment submission. The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

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

II. Background

The NRC received a request for approval of a partial site release from ADP (the licensee), by letter dated February 10, 2025 (ADAMS Package Accession No. ML25041A177). ADP requests NRC approval to remove 618 acres of property, classified as either radiologically non-impacted or Multi-Agency Radiation Survey and Site Investigation Manual Class 3, associated with the Crystal River Unit 3 Operating License No. DPR-72 in accordance with section 50.83 of title 10 of the *Code of Federal Regulations* (10 CFR), "Release of part of a power reactor facility or site for unrestricted use." In addition, the

application requested the NRC to remove another 3,854 acres of property, classified as radiologically non-impacted, from the Crystal River Unit 3 Operating License as approved on January 2, 2020 (ADAMS Accession No. ML19339G509).

The CR3 license (NRC License No. DPR-72, Docket No. 50-302) is for a power reactor under 10 CFR part 50, "Domestic Licensing of Production and Utilization Facilities." The facility was certified as permanently shut down, per NRC regulations in 10 CFR 50.82(a), by letter dated February 20, 2013 (ADAMS Accession No. ML13056A005). ADP is actively decommissioning this site pending the termination of the power reactor license.

As described in 10 CFR 50.83(e), the NRC will determine whether the licensee has adequately evaluated the effect of releasing the properties per the requirements of 10 CFR 50.83(a)(1), determine whether the licensee's classification of any released areas as "non-impacted" is adequately justified, and if the NRC determines that the licensee's submittal is adequate, the NRC will inform the licensee in writing that the release is approved.

III. Request for Comment and Public Meeting

The NRC will conduct a public meeting to answer questions and gather comments regarding ADP's request for approval of the partial site release. The meeting will be held on Wednesday, July 23, 2025, from 5:30 p.m. until 7 p.m. ET, at the Citrus County Chamber of Commerce, located at 915 N Suncoast Blvd., Crystal River, FL 34429.

This is a Category 3 public meeting where stakeholders are invited to fully engage NRC staff to provide a range of views, information, concerns and suggestions with regard to ADP's request for approval of the partial site release. After the licensee and the NRC staff presentation portion of the meeting, the public is allowed to speak and ask questions. Comments can be provided orally or in writing to the NRC staff present at the meeting. The NRC will consider and, if appropriate, respond to these written and verbal comments, but such comments will not otherwise constitute part of the decisional record.

Stakeholders interested in attending this meeting should monitor the NRC's Public Meeting Schedule website at: <https://www.nrc.gov/public-involve/public-meetings/index.cfm> for additional information, meeting agenda and access information for the public meeting.

Dated: June 27, 2025.

For the Nuclear Regulatory Commission.

Shaun Anderson,

*Chief, Reactor Decommissioning Branch,
Division of Decommissioning, Uranium
Recovery and Waste Programs, Office of
Nuclear Material Safety and Safeguards.*

[FR Doc. 2025–12321 Filed 7–1–25; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–395; NRC–2023–0152]

Dominion Energy South Carolina, Inc.; Virgil C. Summer Nuclear Station, Unit 1; Subsequent License Renewal and Record of Decision

AGENCY: Nuclear Regulatory
Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued Subsequent Renewed Facility Operating License No. NPF–12 to Dominion Energy South Carolina, Inc. (DESC, or the licensee), for Virgil C. Summer Nuclear Station, Unit 1 (V.C. Summer). In addition, the NRC has prepared a record of decision (ROD) that supports the NRC’s decision to issue Subsequent Renewed Facility Operating License No. NPF–12.

DATES: The Subsequent Renewed Facility Operating License No. NPF–12 was issued on June 30, 2025.

ADDRESSES: Please refer to Docket ID NRC–2023–0152 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2023–0152. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions

about obtaining materials referenced in this document are provided in the “Availability of Documents” section.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Marieliz Johnson, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5861; email: Marieliz.Johnson@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Discussion

Notice is hereby given that the NRC has issued Subsequent Renewed Facility Operating License No. NPF–12 to DESC for V.C. Summer. Dominion Energy South Carolina, Inc. is the operator of the facility. Subsequent Renewed Facility Operating License No. NPF–12 authorizes operation of V.C. Summer by DESC at reactor core power levels not to exceed 2,900 megawatts thermal (MWt), in accordance with the provisions of the V.C. Summer subsequent renewed license and technical specifications. Notice is also given that the ROD that supports the NRC’s decision to issue Subsequent Renewed Facility Operating License No. NPF–12 is available, and its location is listed in the “Availability of Documents” section of this document.

As discussed in the ROD and the final supplemental environmental impact statement (SEIS), published as NUREG–1437, Supplement 15, Second Renewal, “Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Regarding Subsequent License Renewal for Virgil C. Summer Nuclear Station, Unit 1, Final Report,” published May 2025, the final SEIS documents the NRC staff’s environmental review, including the determination that the adverse environmental impacts of subsequent license renewal (SLR) for V.C. Summer are not so great that preserving the option of SLR for energy planning decisionmakers would be unreasonable. The final SEIS conclusion is based on (1) information provided in the environmental report submitted by DESC, as supplemented; (2) the NRC staff’s consultations with Federal, State, local, and Tribal agencies; (3) the NRC staff’s independent environmental review; and (4) the NRC staff’s consideration of public comments

received during the scoping process and on the 2024 draft SEIS.

V.C. Summer is a pressurized water reactor located near Jenkinsville, South Carolina. DESC submitted its application for the subsequent renewed license, “Virgil C. Summer Nuclear Station, Unit 1, Subsequent License Renewal Application,” on August 17, 2023, as supplemented by letters through October 24, 2024 (see “Availability of Documents” section of this document). The NRC staff has determined that DESC’s application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and NRC’s regulations. As required by the Act and NRC regulations in title 10 of the *Code of Federal Regulations* (10 CFR), the NRC has made the appropriate findings, which are set forth in the subsequent renewed license.

A public notice of the NRC’s acceptance for docketing of the subsequent renewed license application and an opportunity for a hearing was published in the **Federal Register** on October 16, 2023 (88 FR 71384). Further, a notice of intent to prepare a site-specific environmental impact statement and conduct environmental scoping was published on November 3, 2023 (88 FR 75627). On August 6, 2024, the NRC updated the Commission’s 2013 findings on the environmental effects of subsequent renewal of the operating license of a nuclear power plant via rulemaking. This final rule redefines the number and scope of the environmental issues that must be addressed during the review of each application for license renewal (LR) and specifically considers the environmental effects of SLR. As part of this update, the NRC issued Revision 2 to the LR Generic Environmental Impact Statement (GEIS) to account for new information and to address the impacts of initial LR as well as one 20-year period of SLR. The final rule became effective for NRC staff on September 5, 2024. Thereafter, on October 1, 2024, the NRC staff noticed its intent to prepare a plant-specific supplement to the LR GEIS for the V.C. Summer SLR application (89 FR 79975). In November 2024, the NRC staff issued a draft SEIS for public comment, providing the preliminary results of the staff’s environmental evaluation of the V.C. Summer subsequent license renewal application (SLRA). A notice of availability of the draft SEIS was published in the **Federal Register** on December 6, 2024 (89 FR 97077). In January 2025, the NRC staff issued its Safety Evaluation (SE) regarding the V.C. Summer SLRA, and in March 2025,

the NRC staff issued Revision 1 of the SE. In May 2025, the NRC staff issued a final SEIS, providing its final evaluation of the environmental impacts of V.C. Summer SLR; a notice of issuance was published in the **Federal Register** on May 16, 2025 (90 FR 21082).

For further details with respect to this action, see (1) DESC's subsequent

license renewal application for V.C. Summer, dated August 17, 2023, as supplemented by letters dated through October 24, 2024; (2) the NRC's safety evaluation, dated January 21, 2025 and Revision 1, dated March 4, 2025; (3) the NRC's final SEIS (NUREG-1437, Supplement 15, Second Renewal) for

V.C. Summer SLR dated May 2025; and (4) the NRC's ROD, issued in June 2025.

II. Availability of Documents

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

Document Description	Adams Accession No.
Record of Decision—Subsequent License Renewal Application Review—Virgil C. Summer Nuclear Station, Unit 1, dated June 30, 2025..	ML25120A069.
Final Safety Evaluation to the SLRA of Virgil C. Summer Nuclear Station, Unit 1, dated January 21, 2025.	ML25014A307 (Package).
Final Safety Evaluation to the SLRA of Virgil C. Summer Nuclear Station, Unit 1, Revision 1, dated March 4, 2025..	ML25062A234.
NUREG-1437, Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Supplement 15, Second Renewal, Regarding Subsequent License Renewal of Virgil C. Summer Nuclear Station, Unit 1, Final Report, published May 2025..	ML25128A160.
Virgil C. Summer Nuclear Station, Unit 1, Application for Subsequent Renewed Operating License, dated August 17, 2023..	ML23233A179 (Package).
Virgil C. Summer Nuclear Station, Unit 1, Update to Subsequent License Renewal Application (SLRA)—Supplement 1, dated April 1, 2024..	ML24095A207.
Virgil C. Summer Nuclear Station, Unit 1, Update to Subsequent License Renewal Application, Supplement 2, dated May 6, 2024..	ML24129A200.
NUREG-1437, Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Supplement 15, Second Renewal, Regarding Subsequent License Renewal of Virgil C. Summer Nuclear Station, Unit 1, Draft Report for Comment, published November 2024..	ML24330A271.
Virgil C. Summer Nuclear Station, Unit 1, Update to Subsequent License Renewal Application (SLRA)—Response to NRC Request for Additional Information Set 1, Response to NRC Request for Confirmation of Information, Set 1 and Supplement 3, dated May 30, 2024..	ML24155A146.
Virgil C. Summer Nuclear Station, Unit 1, Update to Subsequent License Renewal Application (SLRA)—Response to NRC Request for Additional Information, Set 2 Safety Review, dated June 17, 2024..	ML24171A015.
Virgil C. Summer Nuclear Station, Unit 1, Subsequent License Renewal Application (SLRA)—First 10 CFR 54.21(b) Annual Amendment, dated September 26, 2024..	ML24274A194.
NUREG-1437, Revision 2, Volumes 1, 2, and 3, Generic Environmental Impact Statement for License Renewal of Nuclear Plants, published August 2024..	ML24087A133 (Package).
Virgil C. Summer Nuclear Station, Unit 1, Update to Subsequent License Renewal Application (SLRA)—Supplement 4 and Requested Information Formation in Response to Limited Aging Management Audit, dated October 24, 2024..	ML24302A144.

Dated: June 30, 2025.

For the Nuclear Regulatory Commission.

Samuel Lee,

Deputy Director, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

[FR Doc. 2025-12351 Filed 7-1-25; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2024-0197]

Information Collection: Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB)

approval for an existing collection of information. The information collection is entitled, "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274."

DATES: Submit comments by September 2, 2025. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2024-0197. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301-415-1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Kristen Benney, Office of the Chief Information Officer, Mail Stop: T-6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Kristen Benney, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6355; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2024-0197 when contacting the NRC about the availability of information for this action. You may obtain publicly

available information related to this action by any of the following methods:

- *Federal Rulemaking Website*: Go to <https://www.regulations.gov> and search for Docket ID NRC–2024–0197.
- *NRC's Agencywide Documents Access and Management System (ADAMS)*: You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. The supporting statement is available in ADAMS under Accession No. ML25050A176.
- *NRC's PDR*: The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer*: A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Acting Clearance Officer, Kristen Benney, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6355; email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2024–0197, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

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

the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized as follows.

1. *The title of the information collection*: 10 CFR part 150, "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274."
2. *OMB approval number*: 3150–0032.
3. *Type of submission*: Extension.
4. *The form number, if applicable*: Not applicable.
5. *How often the collection is required or requested*: One-time or as needed.
6. *Who will be required or asked to respond*: Agreement States who have signed section 274(b) Agreements with the NRC.
7. *The estimated number of annual responses*: 9.
8. *The estimated number of annual respondents*: 9.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request*: 190.5.

10. *Abstract*: The NRC regulations in part 150 of title 10 of the *Code of Federal Regulations* (10 CFR), provide certain exemptions to persons in Agreement States from the licensing requirements contained in Chapters 6, 7, and 8 of the Atomic Energy Act of 1954, as amended, and certain regulations of the Commission. The regulations in 10 CFR part 150 also define the Commission's continued regulatory authority over Agreement State activities which include byproduct, source, and special nuclear material reporting requirements related to reciprocity and enforcement. 10 CFR part 150 requires telephonic notification to the NRC when an Agreement State licensee identifies attempted theft or diversion of special nuclear material, byproduct material, and tritium. This notification must be followed by a written report either 15 or 60 days after the initial report, depending on the materials involved. If additional information is available after submission of the written report, an additional report is submitted. These reports are used to inform the Commission, staff, and other Federal agencies when special nuclear material, byproduct material, or tritium is lost or stolen.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.
2. Is the estimate of the burden of the information collection accurate? Please explain your answer.
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: June 30, 2025.

For the Nuclear Regulatory Commission.

Kristen Benney,

Acting NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2025–12349 Filed 7–1–25; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2022–34; CP2024–407; MC2025–1548 and K2025–1542]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 8, 2025.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <https://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Public Proceeding(s)
- III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal

Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are

variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)-(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s).*: CP2022–34; *Filing Title*: Request of the United States Postal Service to Amend Inbound Competitive Multi-Service IRA–USPS II Agreement; *Filing Acceptance Date*: June 27, 2025; *Filing Authority*: 39 CFR 3035.105 and 39 CFR 3041.505; *Public Representative*: Katalin Clendenin; *Comments Due*: July 8, 2025.

2. *Docket No(s).*: CP2024–407; *Filing Title*: USPS Request Concerning Amendment One to Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 138, with Materials Filed Under Seal; *Filing Acceptance Date*: June 27, 2025; *Filing Authority*: 39 CFR 3035.105 and 39 CFR 3041.505; *Public Representative*: Almaroof Agoro; *Comments Due*: July 8, 2025.

3. *Docket No(s).*: MC2025–1548 and K2025–1542; *Filing Title*: USPS Request to Add Priority Mail Contract 899 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: June 27, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Jennaca Upperman; *Comments Due*: July 8, 2025.

III. Summary Proceeding(s)

None. See Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Erica A. Barker,
Secretary.

[FR Doc. 2025–12390 Filed 7–1–25; 8:45 am]

BILLING CODE 7710–FW–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: July 2, 2025.

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 June 26, 2025, 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 74 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2025–1537 and K2025–1531.

Colleen Hibbert-Kapler,
Attorney, Ethics and Legal Compliance.
[FR Doc. 2025–12359 Filed 7–1–25; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail, and USPS Ground Advantage Negotiated Service Agreements; Priority Mail Negotiated Service Agreements

AGENCY: Postal Service.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 2, 2025.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), it filed with the Postal Regulatory Commission the following requests:

¹ See Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Date filed with Postal Regulatory Commission	Negotiated service agreement product category and No.	MC docket No.	K docket No.
6/20/2025	PM-GA 787	MC2025-1534	K2025-1528
6/23/2025	PM 894	MC2025-1535	K2025-1529
6/23/2025	PM-GA 788	MC2025-1536	K2025-1530
6/23/2025	PM-GA 789	MC2025-1538	K2025-1532
6/24/2025	PM 895	MC2025-1539	K2025-1533
6/24/2025	PM-GA 790	MC2025-1540	K2025-1534
6/25/2025	PM 896	MC2025-1541	K2025-1535
6/25/2025	PM 897	MC2025-1542	K2025-1536
6/26/2025	PM-GA 791	MC2025-1543	K2025-1537
6/26/2025	PM-GA 792	MC2025-1544	K2025-1538
6/26/2025	PM-GA 793	MC2025-1545	K2025-1539
6/26/2025	PM 898	MC2025-1547	K2025-1541
6/27/2025	PM 899	MC2025-1548	K2025-1542

Documents are available at
www.prc.gov.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2025-12310 Filed 7-1-25; 8:45 am]

BILLING CODE 7710-12-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-103345; File No. SR-NYSEARCA-2024-87]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 1 to Proposed Rule Change To Amend NYSE Arca Rule 8.500-E and To List and Trade Shares of the Grayscale Digital Large Cap Fund LLC

June 27, 2025.

On October 15, 2024, NYSE Arca, Inc. ("NYSE Arca" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to adopt new NYSE Arca Rule 8.800-E to provide for the listing and trading of Commodity- and Digital Asset-Based Investment Interests and to list and trade shares of the Grayscale Digital Large Cap Fund LLC under proposed NYSE Arca Rule 8.800-E. The proposed rule change was published for comment in the **Federal Register** on November 4, 2024.³

On December 17, 2024, pursuant to Section 19(b)(2) of the Exchange Act,⁴

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.⁵ On January 31, 2025, the Commission instituted proceedings under Section 19(b)(2)(B) of the Exchange Act⁶ to determine whether to approve or disapprove the proposed rule change.⁷ On April 29, 2025, pursuant to Section 19(b)(2) of the Exchange Act,⁸ the Commission designated a longer period for Commission action on proceedings to determine whether to approve or disapprove the proposed rule change.⁹

On June 26, 2025, the Exchange filed with the Commission Amendment No. 1 to proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. Amendment No. 1 replaces and supersedes the proposed rule change as originally filed. The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Arca Rule 8.500-E (Trust Units) and to list and trade shares of the Grayscale Digital Large Cap Fund LLC (the "Fund") under Rule 8.500-E, as

⁵ See Securities Exchange Act Release No. 101939, 89 FR 104581 (Dec. 23, 2024) (designating February 2, 2025, as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change).

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Securities Exchange Act Release No. 102313, 90 FR 9092 (Feb. 6, 2025).

⁸ 15 U.S.C. 78s(b)(2).

⁹ See Securities Exchange Act Release No. 102941, 90 FR 19037 (May 5, 2025) (designating July 2, 2025, as the date by which the Commission shall either approve or disapprove the proposed rule change).

amended. This Amendment No. 1 to SR-NYSEARCA-2024-87 replaces SR-NYSEARCA-2024-87 as originally filed and supersedes such filing in its entirety.¹⁰ 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 III 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

Currently, Rule 8.500-E provides for the listing and trading of Trust Units, which are defined in Rule 8.500-E(b)(2) as securities issued by a trust or other similar entity that is constituted as a commodity pool that holds investments comprising or otherwise based on any combination of futures contracts, options on futures contracts, forward contracts, swap contracts, commodities and/or securities.

The Exchange first proposes to amend Rule 8.500-E(b)(1), which currently

¹⁰ This Amendment No. 1 withdraws the Exchange's original proposal to adopt new NYSE Arca Rule 8.800-E relating to the listing and trading of Commodity- and/or Digital Asset-Based Investment Interests and to list shares of the Fund under such rule.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 101470 (Oct. 29, 2024), 89 FR 87681. Comments on the proposed rule change are available at: <https://www.sec.gov/comments/sr-nysearca-2024-87/srnysearca202487.htm>.

⁴ 15 U.S.C. 78s(b)(2).

provides that the term “commodity,” as used in this Rule, is defined in Section 1(a)(4) of the Commodity Exchange Act. The Exchange proposes to update the reference to Section 1(a)(4) with a reference to Section 1a(9), to accurately reflect the current section reference for the definition of a commodity in the Commodity Exchange Act.

The Exchange next proposes to amend the definition of Trust Units in Rule 8.500–E(b)(2). Specifically, the Exchange proposes that Rule 8.500–E(b)(2) would provide that Trust Units may be issued by a trust, limited liability company, or other similar entity. The Exchange also proposes to specify, by adding the phrase “if applicable,” that the requirement that an entity issuing Trust Units be constituted as a commodity pool will continue to apply, but only with respect to entities that are required to be organized as commodity pools, and to add the word “and” following the term commodity pool to clarify that all entities issuing Trust Units would hold investments as enumerated in Rule 8.500–E(b)(2). The Exchange believes that these proposed changes to broaden the types of entities that could issue Trust Units would afford prospective issuers additional flexibility and encourage the listing and trading of additional series of Trust Units, to the benefit of the investing public.

The Exchange also proposes to amend Rule 8.500–E(c), which currently provides that the Exchange may list and trade Trust Units based on an underlying asset, commodity, security or portfolio. The Exchange proposes to amend Rule 8.500–E(c) to provide that the Exchange may list and trade Trust Units based on an underlying asset, commodity, security, and/or portfolio, which may be represented by an index or portfolio of any of the foregoing. These proposed changes are intended to clarify that Trust Units may be based on an underlying asset, commodity, security, portfolio, or combination thereof, as well as to specify that the underlying components of a series of Trust Units may be represented by an index or portfolio based on an asset, commodity, security, and/or portfolio.

The Exchange further proposes to amend Rule 8.500–E(d)(2)(ii), which currently provides that, upon termination of a trust, the Exchange requires that Trust Units issued in connection with such trust be removed from Exchange listing and that a trust will terminate in accordance with the provisions of the prospectus. Consistent with the proposed change described above to amend Rule 8.500–E to permit Trust Units to be issued by a trust,

limited liability company, or similar entity, the Exchange proposes conforming changes in Rule 8.500–E(d)(2)(ii). Specifically, the Exchange proposes that Rule 8.500–E(d)(2)(ii) would provide that, upon termination of a trust, limited liability company, or other similar entity, the Exchange would require that Trust Units issued in connection with such trust, limited liability company, or other entity be removed from Exchange listing. Rule 8.500–E(d)(2)(ii), as proposed, would also provide that a trust, limited liability company, or other entity issuing Trust Units pursuant to Rule 8.500–E would terminate in accordance with the provisions of the prospectus associated with such series of Trust Units.

The Exchange next proposes to add a new subheading in Rule 8.500–E(d)(3), which currently sets forth continued listing requirements pertaining to the term of a trust issuing Trust Units. The Exchange proposes that Rule 8.500–E(d)(3) would be titled “Trust Units Issued by a Trust,” and that the current text of Rule 8.500–E(d)(3) be designated as new subparagraph (i) to Rule 8.500–E(d)(3). The Exchange further proposes that current Rule 8.500–E(d)(4) (relating to the trustee of a trust issuing Trust Units) be designated as new subparagraph (ii) to Rule 8.500–E(d)(3) and that subparagraphs (i) and (ii) under current Rule 8.500–E(d)(4) be renumbered as new subparagraphs (A) and (B), respectively, below new Rule 8.500–E(d)(3)(ii). In addition, to reflect the consolidation of current Rules 8.500–E(d)(3) and (d)(4), the Exchange proposes to renumber current Rule 8.500–E(d)(5) as Rule 8.500–E(d)(4). The Exchange does not propose any changes to the text of these rules. These proposed changes are intended to clarify the applicability of the requirements set forth in current Rules 8.500–E(d)(3) and (4) to series of Trust Units issued by a trust, specifically.

The Exchange also proposes to amend Rule 8.500–E(e), relating to limitation of Exchange liability. Specifically, the Exchange proposes to amend the first sentence of Rule 8.500–E(e) to add a reference to underlying index value, such that Rule 8.500–E(e) would provide that neither the Exchange nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any underlying portfolio or index value. This proposed change is consistent with the proposed change to Rule 8.500–E(c) described above to specify that the underlying components of a series of Trust Units may be represented by an index or

portfolio based on an asset, commodity, security, and/or portfolio.

The Exchange further proposes to amend Commentary .03 to Rule 8.500–E to specify, consistent with the proposed change to Rule 8.500–E(c) described above to provide that a series of Trust Units may be based on an index, that the Exchange will file separate proposals under Section 19(b) of the Securities Exchange Act of 1934 before listing and trading separate and distinct Trust Units designated on different underlying investments, commodities, assets, indices, and/or portfolios, and that all statements or representations contained in such rule filing regarding the description of the index or portfolio or reference asset will constitute continued listing requirements.

Finally, the Exchange also proposes to amend Rule 5.3–E to include Trust Units listed pursuant to Rule 8.500–E among the derivative or special purpose securities that are subject to a limited set of corporate governance and disclosure policies and to amend Rule 5.3–E(e) to include Trust Units listed pursuant to Rule 8.500–E among the derivative or special purpose securities to which the requirements concerning shareholder/annual meetings do not apply.

Grayscale Digital Large Cap Fund

The Exchange proposes to list and trade shares (“Shares”) ¹¹ of the Fund pursuant to NYSE Arca Rule 8.500–E, as amended.¹²

¹¹ The Shares are expected to be listed under the ticker symbol “GDLC.”

¹² On May 13, 2021, the Fund filed its registration statement on Form 10 under the Securities Act (File No. 000–56284) (the “Registration Statement on Form 10”). On June 28, 2021, the Fund filed Amendment No. 1 to the Registration Statement on Form 10. On August 13, 2021, the Fund filed Amendment No. 2 to the Registration Statement on Form 10. On November 29, 2021, the Fund filed Amendment No. 3 to the Registration Statement on Form 10. On January 20, 2022, the Fund filed Amendment No. 4 to the Registration Statement on Form 10. On February 4, 2022, the Fund filed Amendment No. 5 to the Registration Statement on Form 10. On July 12, 2021, the Registration Statement on Form 10 was automatically deemed effective. On September 27, 2021, September 1, 2022, September 1, 2023, and September 6, 2024, the Fund filed its annual report on Form 10–K under the Securities Act (File No. 000–56284) (the “Annual Reports”). On November 5, 2021, February 10, 2022, May 6, 2022, November 4, 2022, February 8, 2023, May 5, 2023, November 3, 2023, February 7, 2024, May 3, 2024, November 1, 2024, February 5, 2025, and May 2, 2025, the Fund filed its quarterly reports on Form 10–Q under the Securities Act (File No. 000–56284) (the “Quarterly Reports”). On February 7, 2018, the Fund submitted to the Commission a Form D as a limited liability company. Shares of the Fund have been quoted on OTC Market’s OTCQX Best Marketplace under the symbol “GDLC” since October 14, 2019. On October 15, 2019 and September 23, 2020, the Fund

The manager of the Fund is Grayscale Investments Sponsors, LLC (“Manager”), a Delaware limited liability company. The Manager is a wholly owned indirect subsidiary of Digital Currency Group, Inc. (“Digital Currency Group”). The custodian for the Fund is Coinbase Custody Trust Company, LLC (“Custodian”). The administrator and transfer agent of the Fund will be BNY Mellon Asset Servicing, a division of The Bank of New York Mellon (the “Transfer Agent”). The distribution and marketing agent for the Fund will be Foreside Fund Services, LLC (the “Marketing Agent”). The index provider and digital asset index price provider for the Fund is CoinDesk Indices, Inc. (the “Index Provider”).

The Fund is a Cayman Islands limited liability company, formed on January 25, 2018, that operates pursuant to a limited liability company agreement between the Manager and the Shareholders (“LLC Agreement”). The Fund has no fixed termination date.

The Fund is one of the world’s largest diversified crypto investment funds by assets under management as of the date of this filing. The Fund is an SEC reporting company with its Shares registered pursuant to Section 12(g) of the ‘34 Act since July 12, 2021. Shares of the Fund have been quoted on OTC Market’s OTCQX Best Market under the symbol “GDLC” since October 14, 2019. The Fund has approximately \$741.9

published annual reports for GDLC for the periods ended June 30, 2019 and June 30, 2020, respectively. On November 11, 2019, February 13, 2020, May 8, 2020, November 6, 2020, February 12, 2021, and May 13, 2021, the Fund published quarterly reports for GDLC for the periods ended September 30, 2019, December 31, 2019, March 31, 2020, September 30, 2020, December 31, 2020, and March 31, 2021, respectively. Reports published before July 12, 2021, the date on which the Fund’s Shares became registered pursuant to Section 12(g) of the Act, can be found on OTC Market’s website (<https://www.otcm Markets.com/stock/GDLC/disclosure>), and reports published on or after July 12, 2021 can be found on OTC Market’s website and the Commission’s website (<https://www.sec.gov/edgar/browse/?CIK=1729997&owner=exclude>). The Shares will be of the same class and will have the same rights as shares of GDLC. According to Grayscale Investments, LLC, freely tradeable shares of GDLC will remain freely tradeable Shares on the date of the listing of the Shares that are unregistered under the Securities Act. Restricted shares of GDLC will remain subject to private placement restrictions on such date, and the holders of such restricted shares will continue to hold those Shares subject to those restrictions until they become freely tradeable Shares. On April 1, 2025, the Fund filed its registration statement on Form S-3 under the Securities Act (File No. 333-286293) (the “Registration Statement”). On May 16, 2025, the Fund filed Amendment No. 1 to the Registration Statement. On June 6, 2025, the Trust filed Amendment No. 2 to the Registration Statement. The descriptions of the Fund, the Shares, and the digital assets contained herein are based, in part, on the Registration Statement, as amended.

million in assets under management,¹³ and its Shares have historically traded in the millions of dollars in daily volume and are held by more than a quarter of a million American investor accounts seeking exposure to the digital assets held by the Fund (the “Fund Components”) without the cost and complexity of purchasing any of the individual assets directly.¹⁴ As of the date of this filing, the Fund Component weightings are Bitcoin (80.20%), Ether (11.39%), Solana (SOL) (2.78%), XRP (4.82%) and Cardano (ADA) (0.81%).¹⁵ However, because the Fund is not currently listed as an exchange-traded product (“ETP”), the Fund has not been able to operate an ongoing creation and redemption program that would allow the Fund to closely track the value of the Fund’s underlying Fund Components and currently trades at a market price reflecting a discount to its net asset value. The Manager thus believes that allowing Shares of the Fund to list and trade on the Exchange as an ETP (*i.e.*, converting the Fund to a spot ETP) would unlock over \$40 million of value¹⁶ for the Fund’s shareholders and provide other investors with a safe and secure way to invest in the Fund Components on a regulated national securities exchange.

Operation of the Fund

According to the Registration Statement, the Fund’s assets consist solely of the Fund Components.¹⁷ The Fund Components consist of the digital

assets that make up the CoinDesk 5 Index (the “CD5” or “Index”), as rebalanced from time to time, subject to the Manager’s discretion to exclude individual digital assets and/or rebalance the weighting of the Fund Components in certain rules-based circumstances as further described in “Index Components Compared to Fund Components” below.¹⁸ The description of the Fund and Fund Components herein reflects the operation of the Fund as of July 1, 2025.¹⁹

As described in “Determination of the Index Prices” below, each Share represents a proportional interest, based on the total number of Shares outstanding, in each of the Fund Components, as determined by reference to the respective Index Prices and weightings of each Fund Component,²⁰ less the Fund’s expenses and other liabilities (which include accrued but unpaid fees and expenses). The Manager expects that the market price of the Shares will fluctuate over time in response to the market prices of the Fund Components. In addition,

¹⁸ The CD5 is designed and managed by the Index Provider and was formerly known as the CoinDesk Large Cap Select Index (the “DLCS”). Prior to June 5, 2025, the Fund Components consisted of the digital assets that make up the DLCS, as rebalanced from time to time, subject to the Manager’s discretion to exclude individual digital assets and/or rebalance the weightings of Fund Components in certain rules-based circumstances. The DLCS and CD5 apply different criteria to identify the digital assets that may be included in each index and the number of digital assets that may be included in each index, but they otherwise operate similarly in terms of applying market capitalization, liquidity and data availability criteria to such digital assets to select index components and are both intended to represent a diversified benchmark for the largest and most liquid digital assets in the digital asset market. The transition from the DLCS to the CD5 on June 5, 2025 did not result in any change to the Fund Components or the weightings of the Fund Components.

¹⁹ Although the Fund Components reflected the components of the CD5 beginning on June 5, 2025, the Fund will not begin to value the Fund Components based on the CD5 index methodology (as further described below) until July 1, 2025, pursuant to the effectiveness of such methodology as determined by the Index Provider. Shares of the Fund will not list and trade on the Exchange prior to July 1, 2025.

²⁰ As further described below, the value of the Fund Components is determined by reference to their “Index Prices.” The “Index Price” of each Fund Component is the U.S. dollar value of each Fund Component derived from the Digital Asset Trading Platforms (as defined below) that are reflected in each Fund Component’s CoinDesk CCIXber Reference Rate (which will be disseminated by major market data vendors), calculated at 4:00 p.m., New York time, on each business day. As also described further below, the weightings of the Fund Components are generally expected to be the same as the weightings of the components of the CD5, except when the Manager determines to exclude one or more digital assets from the Fund Components and/or rebalance the weighting of the Fund Components in certain rules-based circumstances.

¹³ As of June 20, 2025.

¹⁴ As of the date of this filing.

¹⁵ The Fund Components and their weightings are calculated as if the Fund were operating based on the CoinDesk 5 Index (as further discussed below). The Manager will ensure that the Fund Components are consistent with the requirements set forth in this proposed rule change.

¹⁶ As of June 20, 2025.

¹⁷ The Fund will not obtain exposure to any Fund Component via futures, options on futures, or any other derivative. The Fund may from time to time come into possession of Forked Assets (as defined below) by virtue of its ownership of the Fund Components, generally through a fork in the respective Fund Component’s blockchain, an airdrop offered to holders of the respective Fund Component or other similar event. “Rights to Forked Assets” are rights to acquire, or otherwise establish dominion and control over, any virtual currency or other asset or right, which rights are incident to the Fund’s ownership of the Fund Components and arise without any action of the Fund, or of the Manager on behalf of the Fund. A “Forked Asset” is any virtual currency token, or other asset or right, acquired by the Fund through the exercise (subject to the applicable provisions of the LLC Agreement) of any Rights to Forked Assets. Although the Fund is permitted to take certain actions with respect to Forked Assets in accordance with its LLC Agreement, at this time the Fund will prospectively irrevocably abandon any Forked Assets. In the event the Fund seeks to change this position, the Exchange would file a subsequent proposed rule change with the Commission.

because the Shares reflect the estimated accrued but unpaid expenses of the Fund, except as otherwise affected by a rebalancing of the Fund's portfolio, the number of Fund Components represented by a Share is generally expected to gradually decrease over time as the Fund Components are used to pay the Fund's expenses.

The activities of the Fund are limited to (i) issuing "Baskets" (as defined below) in exchange for Fund Components and cash transferred to the Fund as consideration in connection with creations, (ii) transferring or selling Fund Components as necessary to cover the "Manager's Fee" ²¹ and/or any "Additional Fund Expenses," ²² (iii) transferring Fund Components and cash in exchange for Baskets surrendered for redemption (subject to approval of the Manager), (iv) causing the Manager to sell Fund Components on the termination of the Fund, and (v) engaging in all administrative and security procedures necessary to accomplish such activities in accordance with the provisions of the LLC Agreement, the Custodian Agreement, the Index License Agreement, and the Participant Agreements (each as defined below).²³

²¹ The Manager's Fee means a fee, payable in the Fund Components then held by the Fund in proportion to such Fund Components' respective weightings, which accrues daily in U.S. dollars at an annual rate of currently 2.5%, but which will be lowered in connection with the Fund becoming an ETP, of the NAV Fee Basis Amount of the Fund as of 4:00 p.m., New York time, on each day, provided that for a day that is not a business day, the calculation of the Manager's Fee will be based on the NAV Fee Basis Amount from the most recent business day, reduced by the accrued and unpaid Manager's Fee for such most recent business day and for each day after such most recent business day and prior to the relevant calculation date. The "NAV Fee Basis Amount" is calculated in the manner set forth under "Valuation of Fund Components and Determination of NAV" below.

²² "Additional Fund Expenses" are any expenses incurred by the Fund in addition to the Manager's Fee that are not Manager-paid expenses, including, but not limited to, (i) taxes and governmental charges, (ii) expenses and costs of any extraordinary services performed by the Manager (or any other service provider) on behalf of the Fund to protect the Fund or the interests of shareholders, (iii) any indemnification of the Custodian or other agents, service providers or counterparties of the Fund, (iv) the fees and expenses related to the listing, quotation or trading of the Shares on any marketplace or other alternative trading system, as determined by the Manager, on which the Shares may then be listed, quoted or traded, including but not limited to, NYSE Arca, Inc. (including legal, marketing and audit fees and expenses) to the extent exceeding \$600,000 in any given fiscal year and (v) extraordinary legal fees and expenses, including any legal fees and expenses incurred in connection with litigation, regulatory enforcement or investigation matters.

²³ Neither the Fund, nor the Manager, nor the Custodian, nor any other person associated with the Fund will, directly or indirectly, engage in action where any portion of the Fund Components

The Fund will not be actively managed.²⁴ The Fund will not take any actions to take advantage of, or mitigate, the impacts of volatility in the prices of the Fund Components.

Investment Objective

According to the Registration Statement, and as further described below, the Fund's investment objective is for the value of the Shares (based on net asset value ("NAV") per Share) to reflect the value of the Fund Components held by the Fund, as determined by reference to their Index Prices and weightings within the Fund, less the Fund's expenses and other liabilities. As further discussed below, the weightings of the Fund Components are generally expected to be the same as the weightings of the components of the CD5, except when the Manager determines to exclude one or more digital assets from the Fund Components and/or rebalance the weighting of the Fund Components in certain rules-based circumstances as further described in "Index Components Compared to Fund Components" below.

While an investment in the Shares is not a direct investment in the Fund Components, the Shares are designed to provide investors with a cost-effective and convenient way to gain investment exposure to the Fund Components. Generally speaking, a substantial direct investment in the Fund Components may require expensive and sometimes complicated arrangements in connection with the acquisition, security and safekeeping of the Fund Components and may involve the payment of substantial fees to acquire such Fund Components from third-party facilitators through cash payments of U.S. dollars. Because the value of the Shares is correlated with the value of Fund Components held by the Fund, it is important to understand the investment attributes of, and the market for, the Fund Components.

The Fund uses the Index Price of each Fund Component to calculate its NAV, which is the aggregate value, expressed in U.S. dollars, of the Fund's assets, less the U.S. dollar value of the Fund's expenses and other liabilities calculated in the manner set forth under "Valuation of Fund Components and

becomes subject to proof-of-stake validation or is used to earn additional Fund Components or generate income or other earnings.

²⁴ The Fund is a passive entity that is managed and administered by the Manager and does not have any officers, directors or employees. The Manager will retain limited discretion to exclude digital assets from the Fund Components and/or rebalance the weighting of the Fund Components only in certain rules-based circumstances, as further discussed below.

Determination of NAV." "NAV per Share" is calculated by dividing NAV by the number of Shares then outstanding.

Valuation of Fund Components and Determination of NAV

The following is a description of the material terms of the LLC Agreement as it relates to valuation of the Fund digital assets and the NAV calculations.²⁵

At 4:00 p.m., New York time, on each business day or as soon thereafter as practicable, the Manager will evaluate the Fund Components held by the Fund and calculate and publish the NAV of the Fund. To calculate the NAV, the Manager will:

1. For each Fund Component then held by the Fund:

a. Determine the Index Price for the Fund Component as of such business day;

b. Multiply the Index Price by the aggregate number of tokens of the Fund Component held by the Fund as of 4:00 p.m., New York time, on the immediately preceding business day;

c. Add the U.S. dollar value of the number of tokens of the Fund Component receivable under pending creation orders, if any, as calculated by multiplying the applicable Fund Component Basket Amount ²⁶ by the applicable Index Price, and multiplying the result by the number of Baskets pending under such pending creation orders; and

d. Subtract the U.S. dollar value of the number of tokens of the Fund Component to be distributed under pending redemption orders, if any, as calculated by multiplying the applicable

²⁵ While the Manager uses the terminology "NAV" in this filing, the term used in the LLC Agreement is "Digital Asset Holdings."

²⁶ "Fund Component Basket Amount" means, as of any trade date, the amount of tokens of such Fund Component required to be delivered in connection with each Creation Basket, as determined by dividing the amount of tokens of such Fund Component held by the Fund at 4:00 p.m., New York time, on such trade date, after deducting the applicable Fund Component Aggregate Liability Amount (defined below), by the number of Shares outstanding at such time (the quotient so obtained calculated to one one-hundred-millionth (*i.e.*, carried to the eighth decimal place)) and multiplying the quotient so obtained for the Fund Component by 100. "Fund Component Aggregate Liability Amount" means for any Fund Component and any trade date, an amount of tokens of such Fund Component equal to the sum of (x) all accrued but unpaid Fund Component Fee Amounts for such Fund Component as of 4:00 p.m., New York time, on such trade date and (y) the Fund Component Expense Amount as of 4:00 p.m., New York time, on such trade date. The "Fund Component Fee Amount" is the amount of tokens of each Fund Component payable as the Manager's Fee for any day. The "Fund Component Expense Amount" is the amount of tokens of each Fund Component payable as expenses for any day.

Fund Component Basket Amount by the applicable Index Price, and multiplying the result by the number of Baskets pending under such pending redemption orders;²⁷

2. Calculate the sum of the resulting U.S. dollar values for all Fund Components then held by the Fund, as determined pursuant to paragraph 1 above;

3. Add (i) the amount of U.S. dollars then held by the Fund plus (ii) the amount of any U.S. dollars to be received by the Fund in connection with any pending creations;

4. Subtract the amount of any U.S. dollars to be distributed under pending redemption orders;

5. Subtract the U.S. dollar amount of accrued and unpaid Additional Fund Expenses, if any;

6. Subtract the U.S. dollar value of the accrued and unpaid Manager's Fee as of 4:00 p.m., New York time on the immediately preceding business day (the amount derived from steps 1 through 6, the "NAV Fee Basis Amount"); and

7. Subtract the U.S. dollar value of the accrued and unpaid Manager's Fee that accrues for such business day, as calculated based on the NAV Fee Basis Amount for such business day.

Notwithstanding the foregoing, in the event that the Manager determines that the primary methodology used to determine any of the Index Prices is not an appropriate basis for valuation of the Fund's digital assets, the Manager will utilize the cascading set of rules as described in "Determination of the Index Prices" below.

Background on Current Fund Components²⁸

Bitcoin and the Bitcoin Network

Bitcoin is a digital asset that is created and transmitted through the operations of the peer-to-peer Bitcoin network, a decentralized network of computers that operates on cryptographic protocols. No single entity owns or operates the Bitcoin network, the infrastructure of which is collectively maintained by a decentralized user base. The Bitcoin network allows people to exchange tokens of value, called Bitcoin, which are recorded on a public transaction ledger known as a blockchain. Bitcoin can be used to pay for goods and services, or it can be converted to fiat currencies, such as the U.S. dollar, at

rates determined on Digital Asset Markets²⁹ that trade Bitcoin or in individual end-user-to-end-user transactions under a barter system.

The Bitcoin network was initially contemplated in a white paper that also described Bitcoin and the operating software to govern the Bitcoin network. The white paper was purportedly authored by Satoshi Nakamoto. However, no individual with that name has been reliably identified as Bitcoin's creator, and the general consensus is that the name is a pseudonym for the actual inventor or inventors. The first Bitcoins were created in 2009 after Nakamoto released the Bitcoin network source code (the software and protocol that created and launched the Bitcoin network). The Bitcoin network has been under active development since that time by a group of engineers known as core developers. The core developers are able to access, and can alter, the Bitcoin network source code and, as a result, they are responsible for quasi-official releases of updates and other changes to the Bitcoin network's source code. The release of updates to the Bitcoin network's source code does not guarantee that the updates will be automatically adopted. Users and miners must accept any changes made to the Bitcoin source code by downloading the proposed modification of the Bitcoin network's source code. A modification of the Bitcoin network's source code is effective only with respect to the Bitcoin users and miners that download it. If a modification is accepted by only a percentage of users and miners, a division in the Bitcoin network will occur such that one network will run the pre-modification source code and the other network will run the modified source code. Such a division is known as a "fork."

Core development of the Bitcoin network source code has increasingly focused on modifications of the Bitcoin network protocol to increase speed and scalability and also allow for non-financial, next generation uses. For example, following the activation of

Segregated Witness on the Bitcoin network, an alpha version of the Lightning network was released. The Lightning network is an open-source decentralized network that enables instant off-blockchain transfers of the ownership of Bitcoin without the need of a trusted third party. The system utilizes bidirectional payment channels that consist of multi-signature addresses. One on-blockchain transaction is needed to open a channel and another on-blockchain transaction can close the channel. Once a channel is open, value can be transferred instantly between counterparties who are engaging in real Bitcoin transactions without broadcasting them to the Bitcoin network. New transactions will replace previous transactions and the counterparties will store everything locally as long as the channel stays open to increase transaction throughput and reduce computational burden on the Bitcoin network. Other efforts include increased use of smart contracts and distributed registers built into, built atop or pegged alongside the Bitcoin blockchain. For example, the white paper for Blockstream, an organization that includes core developer Pieter Wuille, calls for the use of "pegged sidechains" to develop programming environments that are built within Bitcoin blockchain ledgers that can interact with and rely on the security of the Bitcoin network and the Bitcoin blockchain, while remaining independent from them. Open-source projects such as RSK are a manifestation of this concept and seek to create the first open-source, smart contract platform built on the Bitcoin blockchain to enable automated, condition-based payments with increased speed and scalability. At this time, such projects remain in early stages and have not been materially integrated into the Bitcoin blockchain or the Bitcoin network. The Fund's activities will not directly relate to such projects, though such projects may utilize Bitcoin as tokens for the facilitation of their non-financial uses, thereby potentially increasing demand for Bitcoin and the utility of the Bitcoin network as a whole. Conversely, projects that operate and are built within the blockchain may increase the data flow on the Bitcoin network and could either "bloat" the size of the Bitcoin blockchain or slow confirmation times.

The supply of new Bitcoin is mathematically controlled so that the number of Bitcoin grows at a limited rate pursuant to a pre-set schedule. The number of Bitcoin awarded for solving a new block is automatically halved

²⁷ "Baskets" and "Basket Amount" have the meanings set forth in "Creation and Redemption of Shares" below.

²⁸ The description of the Fund Components in this section was provided by the Manager and is based on the Registration Statement.

²⁹ A "Digital Asset Market" is a "Brokered Market," "Dealer Market," "Principal-to-Principal Market" or "Exchange Market" (referred to as "Trading Platform Markets" in this proposal), as each such term is defined in the Financial Accounting Standards Board Accounting Standards Codification Master Glossary. The "Digital Asset Trading Platform Market" is the global trading platform market for the trading of digital assets, which consists of transactions on electronic Digital Asset Trading Platforms. A "Digital Asset Trading Platform" is an electronic marketplace where trading platform participants may trade, buy and sell digital assets based on bid-ask trading. The largest Digital Asset Trading Platforms are online and typically trade on a 24-hour basis, publishing transaction price and volume data.

after every 210,000 blocks are added to the blockchain. Currently, the fixed reward for solving a new block is 3.125 Bitcoin per block and this is expected to decrease by half to become 1.5625 Bitcoin after the next 210,000 blocks have entered the Bitcoin Network, which is expected to be mid-2028. This deliberately controlled rate of Bitcoin creation means that the number of Bitcoin in existence will increase at a controlled rate until the number of Bitcoin in existence reaches the pre-determined 21 million Bitcoin. As of March 31, 2025, approximately 19.8 million Bitcoins were outstanding and the date when the 21 million Bitcoin limitation will be reached is estimated to be the year 2140.

Ether and the Ethereum Network

Ether is a digital asset that is created and transmitted through the operations of the peer-to-peer “Ethereum Network,” a decentralized network of computers that operates on cryptographic protocols. No single entity owns or operates the Ethereum Network, the infrastructure of which is collectively maintained by a decentralized user base. The Ethereum Network allows people to exchange tokens of value, called Ether, which are recorded on a public transaction ledger known as a blockchain. Ether can be used to pay for goods and services, including computational power on the Ethereum Network, or it can be converted to fiat currencies, such as the U.S. dollar, at rates determined on Digital Asset Markets or in individual end-user-to-end-user transactions under a barter system.

Furthermore, the Ethereum Network also allows users to write and implement smart contracts—that is, general-purpose code that executes on every computer in the network and can instruct the transmission of information and value based on a sophisticated set of logical conditions. Using smart contracts, users can create markets, store registries of debts or promises, represent the ownership of property, move funds in accordance with conditional instructions and create digital assets other than Ether on the Ethereum Network. Smart contract operations are executed on the Ethereum blockchain in exchange for payment of Ether. The Ethereum Network is one of a number of projects intended to expand blockchain use beyond just a peer-to-peer money system.

The Ethereum Network went live on July 30, 2015.

Smart Contracts and Development on the Ethereum Network

Smart contracts are programs that run on a blockchain that can execute automatically when certain conditions are met. Smart contracts facilitate the exchange of anything representative of value, such as money, information, property, or voting rights. Using smart contracts, users can send or receive digital assets, create markets, store registries of debts or promises, represent ownership of property or a company, move funds in accordance with conditional instructions and create new digital assets.

Development on the Ethereum Network involves building more complex tools on top of smart contracts, such as decentralized apps (“DApps”); organizations that are autonomous, known as decentralized autonomous organizations (“DAOs”); and entirely new decentralized networks. For example, a company that distributes charitable donations on behalf of users could hold donated funds in smart contracts that are paid to charities only if the charity satisfies certain pre-defined conditions.

Moreover, the Ethereum Network has also been used as a platform for creating new digital assets and conducting their associated initial coin offerings. As of March 31, 2025, a majority of digital assets were built on the Ethereum Network, with such assets representing a significant amount of the total market value of all digital assets.

More recently, the Ethereum Network has been used for decentralized finance (“DeFi”) or open finance platforms, which seek to democratize access to financial services, such as borrowing, lending, custody, trading, derivatives and insurance, by removing third-party intermediaries. DeFi can allow users to lend and earn interest on their digital assets, exchange one digital asset for another and create derivative digital assets such as stablecoins, which are digital assets pegged to a reserve asset such as fiat currency. Over the course of 2024, between \$29 billion and \$79 billion worth of digital assets were locked up as collateral on DeFi platforms on the Ethereum Network.³⁰

SOL and the Solana Network

The Solana protocol introduced the Proof-of-History (“PoH”) consensus mechanism as an alternative to Proof-of-Stake (“PoS”) blockchains like Ethereum and Proof-of-Work (“PoW”)

blockchains like Bitcoin.³¹ PoH is a consensus mechanism that automatically orders on-chain transactions by creating a historical record that proves an event has occurred at a specific moment in time. PoH is intended to provide a transaction processing speed and capacity advantage over traditional PoW and PoS networks, which rely on sequential production of blocks and can lead to delays caused by validator confirmations.

The Solana protocol was first conceived by Anatoly Yakovenko in a 2017 whitepaper. Development of the Solana network is overseen by the Solana Foundation, a Swiss non-profit organization, and Solana Labs, Inc., a Delaware corporation, which administered the original network launch and token distribution. Smart contract operations are executed on the Solana blockchain in exchange for payment of SOL.

XRP and the XRP Network

XRP is a digital asset that was created by Chris Larsen, Jed McCaleb, Arthur Britto and David Schwartz (the “XRP Creators”) in 2012. Built out of the frustrations of Bitcoin’s utility for payments, the XRP ledger (the ledger to which XRP is native) is designed to be a global real-time payment and settlement system. The XRP Creators developed this unique digital asset to solve the scalability concerns that they believed were inherent in the structure of Bitcoin. In particular, XRP was created to improve the efficiency of payments. To this end, the open source code (available at <https://github.com/ripple/rippled/>) was designed to maximize speed, scalability, and stability.

For example, the XRP ledger can accommodate 4,400 transactions per second. This is, in part, because XRP is not mined like Bitcoin, but is designed for the ledgers to close in seconds based on a system of consensus. Further, because of the consensus methodology underlying the XRP design, network transaction fees are substantially lower than Bitcoin, typically less than \$0.01.

Given the unique qualities of XRP and the natural suitability of this digital asset to solve the friction experience with payments, the XRP Creators started a company, calling it Ripple, to further develop the ecosystem around XRP and

³⁰ DeFiLlama, “Ethereum Total Value Locked,” <https://defillama.com/chain/Ethereum>.

³¹ Neither the Fund, nor the Manager, nor the Custodian, nor any other person associated with the Fund will, directly or indirectly, engage in action where any portion of the Fund’s Fund Components becomes subject to proof-of-stake validation or is used to earn additional Fund Components or generate income or other earnings.

build software solutions to address the friction in sending, processing, and sourcing liquidity for global payments. Thus, the company, Ripple, began as, and continues to be, a payments software company. Today, Ripple is focused on designing and deploying state-of-the-art and industry-leading software to enable banks and financial institutions to more easily effect cross-border payments. For maximum efficiency, Ripple's software can integrate XRP to solve liquidity and value transfer challenges.

ADA and the Cardano Network

ADA is a digital asset that is created and transmitted through the operations of the peer-to-peer Cardano network, a decentralized network of computers that operates on cryptographic protocols. No single entity owns or operates the Cardano network, the infrastructure of which is collectively maintained by a decentralized user base. The Cardano network allows people to exchange tokens of value, called ADA, which are recorded on a public transaction ledger known as a blockchain. ADA can be used to pay for goods and services, including computational power on the Cardano network, or it can be converted to fiat currencies, such as the U.S. dollar, at rates determined on digital asset exchanges or in individual end-user-to-end-user transactions under a barter system.

Furthermore, the Cardano network was designed to allow users to write and implement smart contracts—that is, general-purpose code that executes on every computer in the network and can instruct the transmission of information and value based on a sophisticated set of logical conditions. Using smart contracts, users can create markets, store registries of debts or promises, represent the ownership of property, move funds in accordance with conditional instructions and create digital assets other than ADA on the Cardano network. Smart contract operations are executed on the Cardano blockchain in exchange for payment of ADA. Like the Ethereum Network, the Cardano network is one of a number of projects intended to expand blockchain use beyond just a peer-to-peer money system.

Cardano was founded by Charles Hoskinson, a co-founder of the Ethereum Network. Development of the Cardano network is overseen by the Cardano Foundation, a Swiss non-profit organization that administered the original network launch and token distribution. The Cardano Foundation has contracted IOHK, a company founded by Hoskinson, to continue

building and maintaining the Cardano network.

Custody of the Fund Components

Digital assets and digital asset transactions are recorded and validated on blockchains, the public transaction ledgers of a digital asset network. Each digital asset blockchain serves as a record of ownership for all of the units of such digital asset, even in the case of certain privacy-preserving digital assets, where the transactions themselves are not publicly viewable. All digital assets recorded on a blockchain are associated with a public blockchain address, also referred to as a digital wallet. Digital assets held at a particular public blockchain address may be accessed and transferred using a corresponding private key.

Key Generation

Public addresses and their corresponding private keys are generated by the Custodian in secret key generation ceremonies at secure locations inside faraday cages, which are enclosures used to block electromagnetic fields and thus mitigate against attacks. The Custodian uses quantum random number generators to generate the public and private key pairs.

Once generated, private keys are encrypted, separated into “shards,” and then further encrypted. After the key generation ceremony, all materials used to generate private keys, including computers, are destroyed. All key generation ceremonies are performed offline. No party other than the Custodian has access to the private key shards of the Fund, including the Fund itself.

Key Storage

Private key shards are distributed geographically in secure vaults around the world, including in the United States. The locations of the secure vaults may change regularly and are kept confidential by the Custodian for security purposes.

The “Digital Asset Account” is a segregated custody account controlled and secured by the Custodian to store private keys, which allows for the transfer of ownership or control of the Fund's Fund Components on the Fund's behalf. The Digital Asset Account uses offline storage, or “cold storage,” mechanisms to secure the Fund's private keys. The term cold storage refers to a safeguarding method by which the private keys corresponding to digital assets are disconnected and/or deleted entirely from the internet. Cold storage of private keys may involve

keeping such keys on a non-networked (or “air-gapped”) computer or electronic device or storing the private keys on a storage device (for example, a USB thumb drive) or printed medium (for example, papyrus, paper, or a metallic object). A digital wallet may receive deposits of digital assets but may not send digital assets without use of the digital assets' corresponding private keys. In order to send digital assets from a digital wallet in which the private keys are kept in cold storage, either the private keys must be retrieved from cold storage and entered into an online, or “hot,” digital asset software program to sign the transaction, or the unsigned transaction must be transferred to the cold server in which the private keys are held for signature by the private keys and then transferred back to the online digital asset software program. At that point, the user of the digital wallet can transfer its digital assets.

Security Procedures

The Custodian is the custodian of the Fund's private keys (which, as noted above, facilitate the transfer of ownership or control of the Fund Components) in accordance with the terms and provisions of the custodian agreement by and between the Custodian, the Manager and the Fund (the “Custodian Agreement”). Transfers from the Digital Asset Account require certain security procedures, including, but not limited to, multiple encrypted private key shards, usernames, passwords and 2-step verification. Multiple private key shards held by the Custodian must be combined to reconstitute the private key to sign any transaction in order to transfer the Fund's assets. Private key shards are distributed geographically in secure vaults around the world, including in the United States.

As a result, if any one secure vault is ever compromised, this event will have no impact on the ability of the Fund to access its assets, other than a possible delay in operations, while one or more of the other secure vaults is used instead. These security procedures are intended to remove single points of failure in the protection of the Fund's assets.

Transfers of Fund Components to the Digital Asset Account will be available to the Fund once processed on the relevant blockchain.

Subject to authorization of the Manager, the process of accessing and withdrawing Fund Components from the Fund to redeem a Basket by an

Authorized Participant³² will follow the same general procedure as transferring Fund Components to the Fund to create a Basket by an Authorized Participant, only in reverse.

The Manager will maintain ownership and control of the Fund Components in a manner consistent with good delivery requirements for spot commodity transactions.

Fund Component Value

Digital Asset Trading Platform Valuation

According to the Registration Statement, the value of digital assets is determined by the value that various market participants place on digital assets through their transactions. The most common means of determining the value of a digital asset is by surveying one or more Digital Asset Trading Platforms where the digital asset is traded publicly and transparently (*e.g.*, Coinbase, Kraken, LMAX Digital, Crypto.com, and Bitstamp).³³

Digital Asset Trading Platform Public Market Data

On each online Digital Asset Trading Platform, digital assets are traded with publicly disclosed valuations for each executed trade, measured by one or more fiat currencies such as the U.S. dollar or Euro, or by the digital asset Bitcoin. Over-the-counter dealers or market makers do not typically disclose their trade data.

As of March 31, 2025, the Digital Asset Trading Platforms included in the Index Prices were Bitfinex, Bitstamp, Bullish, Bybit, Crypto.com, Gemini, itBit, Kraken, LMAX Digital, and OKX.³⁴ As further described below, the Manager and the Fund believe each of these Digital Asset Trading Platforms are in material compliance with applicable licensing requirements based on the “Trading Platform Category” (as defined below) and jurisdiction, as detailed below, and maintain practices and policies designed to comply with anti-money laundering (“AML”) and know-your-customer (“KYC”) regulations.

Bitstamp: A U.K.-based trading platform that has U.S. operations and entities registered as money services businesses (“MSBs”) with the U.S. Department of the Treasury’s Financial Crimes Enforcement Network

(“FinCEN”), holds a BitLicense, and that is licensed as a money transmitter in various U.S. states.

Bitfinex: A British Virgin Islands based trading platform. Bitfinex does not hold any licenses or registrations in the U.S. and is not available to U.S.-based customers. Bitfinex is categorized by the Index Provider as a “Category 2” trading platform that meets the Inclusion Criteria³⁵ but is non-U.S. licensed.

Bullish: A Gibraltar-based trading platform that has entities registered as MSBs with FinCEN. Bullish is not available to U.S.-based customers. Bullish is categorized by the Index Provider as a “Category 2” trading platform that meets the Inclusion Criteria outlined below but is non-U.S. licensed.

Bybit: A United Arab Emirates-based trading platform. Bybit does not hold any licenses or registrations in the U.S. and is not available to U.S. based customers. Bybit is categorized by the Index Provider as a “Category 2” trading platform that meets the Inclusion Criteria but is non-U.S. licensed.

Crypto.com: A Singapore-based trading platform that has entities registered as MSBs with FinCEN, and that is licensed as a money transmitter in various U.S. states and chartered as a non-depository trust company by the New Hampshire Banking Department. Crypto.com does not hold a BitLicense.

Gemini: A U.S.-based trading platform that has entities registered as MSBs with FinCEN and that is licensed as a money transmitter in various U.S. states. Gemini is exempt from applying for a BitLicense under the framework established by the New York Department of Financial Services (“NYDFS”) because of their trust charter under New York Banking Law.

itBit: A U.S.-based trading platform that has entities registered as MSBs with FinCEN and that is licensed as a limited purpose trust company under the NYDFS through its parent company, Paxos Trust Company, LLC. itBit does not hold a BitLicense.

Kraken: A U.S.-based trading platform that has entities registered as MSBs with FinCEN, and that is licensed as a money transmitter in various U.S. states and chartered as a Special Purpose Depository Institution by the Wyoming Division of Banking. Kraken does not hold a BitLicense.

LMAX Digital: A U.K.-based trading platform that has entities registered as a

broker with the U.K. Financial Conduct Authority, and that is licensed as an MSB with FinCEN and regulated by the Gibraltar Financial Services Commission.

OKX: A Seychelles-based trading platform. OKX does not hold any licenses or registrations in the U.S. and is not available to U.S.-based customers. OKX is categorized by the Index Provider as a “Category 2” trading platform that meets the Inclusion Criteria but is non-U.S. licensed.

Currently, there are several Digital Asset Trading Platforms operating worldwide, and online Digital Asset Trading Platforms represent a substantial percentage of buying and selling activity and provide the most data with respect to prevailing valuations of the Fund Components. These trading platforms include established trading platforms such as trading platforms included in the Index Prices, which provide a number of options for buying and selling the Fund Components. The below tables reflect the trading volume in each Fund Component and market share³⁶ of the

³⁶ Bitcoin market share is calculated using trading volume (in Bitcoin) for certain Digital Asset Trading Platforms, including Bitfinex, Bitstamp, Bullish, Bybit, Crypto.com, Gemini, itBit, Kraken, LMAX Digital and OKX, as well as certain other large U.S.-dollar and USDC denominated Digital Asset Trading Platforms that were not included in the Index Price as of March 31, 2025, including Binance, Binance.US, Bitflyer, CEX.IO, Coinbase, Deribit, Huobi, Kucoin, Lbank, MEXC and Deribit. Ether market share is calculated using trading volume (in Ether) for certain Digital Asset Trading Platforms, including Bitfinex, Bitstamp, Bullish, Bybit, Crypto.com, Gemini, itBit, Kraken, LMAX Digital and OKX, as well as certain other large U.S.-dollar and USDC denominated Digital Asset Trading Platforms that were not included in the Index Price as of March 31, 2025, including Binance, Binance.US, Bitflyer, CEX.IO, Coinbase, Deribit, Gemini, HitBTC, Huobi, itBit, KuCoin, Lbank, LMAX Digital, MEXC, and OKCoin. SOL market share is calculated using trading volume (in SOL) for certain Digital Asset Trading Platforms, including Bitfinex, Bitstamp, Bullish, Bybit, Crypto.com, Gemini, itBit, Kraken, LMAX Digital, and OKX, as well as certain other large U.S. dollar and USDC denominated Digital Asset Trading Platforms that were not included in the Index Price as of March 31, 2025, including Binance, Binance.US, CEX.IO, Coinbase, Deribit, Gate.IO, KuCoin, Lbank, and MEXC. ADA market share is calculated using trading volume (in ADA) for certain Digital Asset Trading Platforms, including Bitfinex, Bitstamp, Bybit, Crypto.com, Kraken, and OKX, as well as certain other large U.S. dollar and USDC denominated Digital Asset Trading Platforms that were not included in the Index Price as of March 31, 2025, including Binance, Binance.US, Coinbase, Gate.IO, HitBTC, KuCoin, and MEXC. XRP market share is calculated using trading volume (in XRP) for certain Digital Asset Trading Platforms, including Bitfinex, Bitstamp, Bullish, Bybit, Crypto.com, Gemini, Kraken, LMAX Digital, and OKX, as well as certain other large U.S. dollar and USDC denominated Digital Asset Trading Platforms that were not included in the Index Price as of March 31, 2025, including Bibox, Binance, Binance.US, Coinbase, Deribit, Gate.IO, KuCoin, Lbank, and MEXC.

³² “Authorized Participant” has the meaning set forth in “Creation and Redemption of Shares” below.

³³ Over-the-counter dealers and market makers may also transact in digital assets.

³⁴ The Digital Asset Trading Platforms included in the Index Prices may vary, and not all Digital Asset Trading Platforms are included in each Index Price.

³⁵ The “Inclusion Criteria” are criteria applied by the Index Provider to determine whether a trading platform is eligible to become a Constituent Trading Platform, as further discussed in “Constituent Trading Platform Selection” below.

Fund Component-U.S. dollar and Fund
Component-USD Coin ("USDC") trading
pairs of each of the Digital Asset

Trading Platforms included in the Index
Prices as of March 31, 2025
(collectively, "Constituent Trading

Platforms"), using data reported by the
Index Provider from January 1, 2024 to
March 31, 2025:

Bitcoin trading platforms included in the Index Price as of March 31, 2025	Volume (Bitcoin)	Market share (%)
Crypto.com	5,649,095	35.01
Kraken	1,054,839	6.54
Bitstamp	962,978	5.97
LMAX Digital	909,192	5.64
Bitfinex	624,078	3.87
Bullish	561,913	3.48
Gemini	357,780	2.22
itBit	75,869	0.47
OKX	14,817	0.09
Total Bitcoin-U.S. Dollar trading pair	10,210,559	63.28
Bullish	3,802,861	39.47
Bybit	2,831,696	29.39
OKX	624,904	6.49
Kraken	48,807	0.51
Bitstamp	6,184	0.06
Total Bitcoin-USDC trading pair	7,314,452	75.91
Ether trading platforms included in the Index Price as of March 31, 2025	Volume (Ether)	Market share (%)
Crypto.com	147,382,677	62.57
LMAX Digital	8,517,589	3.62
Kraken	7,881,802	3.35
Bullish	7,763,216	3.30
Bitstamp	3,606,634	1.53
Bitfinex	3,529,425	1.50
Gemini	2,839,061	1.21
itBit	755,172	0.32
OKX	597,631	0.25
Total Ether-U.S. Dollar trading pair	182,873,207	77.63
Bybit	49,754,266	21.12
Bullish	43,462,680	18.45
OKX	8,970,449	3.81
Kraken	381,191	0.16
Bitstamp	32,379	0.01
Total Ether-USDC trading pair	102,600,965	43.56
SOL trading platforms included in the Index Price as of March 31, 2025	Volume (SOL)	Market share (%)
Kraken	180,697,333	21.26
Crypto.com	63,266,934	7.44
LMAX Digital	30,571,876	3.60
Bitstamp	19,768,722	2.33
Gemini	13,116,265	1.54
Bitfinex	12,411,935	1.46
Bullish	3,443,144	0.41
itBit	2,056,975	0.24
OKX	1,553,079	0.18
Total SOL-U.S. Dollar trading pair	326,886,263	38.46
Bybit	66,734,820	23.48
OKX	25,311,560	8.90
Bullish	23,783,549	8.37
Kraken	1,803,180	0.63
Total SOL-USDC trading pair	117,633,109	41.38

Trading Platforms included in the Index Price as of March 31, 2025	Volume (ADA)	Market share (%)
Kraken	5,074,914,798	17.24
Crypto.com	2,606,371,671	8.86
Bitfinex	856,345,067	2.91
Bitstamp	599,531,930	2.04
Total ADA-U.S. Dollar trading pair	9,137,163,466	31.05
Bybit	1,141,907,555	10.14
OKX	488,344,223	4.34
Kraken	113,409,303	1.01
Total ADA-USDC trading pair	1,743,661,080	15.49

XRP Trading Platforms included in the Index Price as of March 31, 2025	Volume (XRP)	Market share (%)
Crypto.com	12,847,158,745	13.76
Kraken	11,222,742,450	12.02
Bitstamp	6,621,938,727	7.09
LMAX Digital	5,340,528,253	5.72
Bitfinex	1,684,516,016	1.80
Gemini	868,329,195	0.93
OKX	84,362,827	0.09
Total XRP-U.S. Dollar trading pair	38,669,576,213	41.41
Bullish	21,913,561,282	54.49
Bybit	5,147,733,555	12.80
OKX	2,157,197,958	5.36
Kraken	81,385,761	0.20
Total XRP-USDC trading pair	29,299,878,556	72.86

The domiciles of, as well as the regulations and laws applicable to, the Digital Asset Trading Platforms included in the Index Prices vary. Information regarding each Digital Asset Trading Platform may be found, where available, on the websites for such Digital Asset Trading Platforms, among other places.

The Index and Index Prices

The digital assets that make up the CD5 (the "Index Components") are drawn from the universe of investable digital assets meeting the following criteria (the "Index Universe"): (i) the digital asset must be ranked in the top 250 by market capitalization, excluding stablecoins; (ii) the digital asset must be able to support an applicable index price by nature of its inclusion on a sufficient amount of digital asset trading platforms and volume metrics; (iii) the digital asset must not be a "wrapped token," "pegged token," or "liquid-staked asset," a "gas-only token," a "memecoin," a "privacy-focused" token, each as defined by the Index Provider, or an asset that meets the definition of a security as determined by the Index Provider; and (iv) the digital asset must be listed as a USD and/or USDC pair on a minimum of three trading platforms that contribute to the

applicable Index Price and such trading platform must meet the following requirements: (a) at least one listing has existed for the previous 90 days; (b) at least one digital trading platform is a Category 1 Trading Platform (as defined below); and (c) there has been 30 consecutive days of non-zero volume on all three trading platforms described above.

The Index Provider applies market capitalization, liquidity and data availability criteria to the digital assets in the Index Universe in order to arrive at five digital assets that, in the Index Provider's judgment, represent a diversified benchmark for the largest and most liquid digital assets in the digital asset market (the "Large Cap Sector"), rather than exposure to all digital assets in the Index Universe. The respective weightings of the Index Components within the CD5 are determined by the Index Provider based on market capitalization criteria and are referred to as the "Index Weightings." The process followed by the Index Provider to determine the Index Universe, the Index Components and their respective Index Weightings is referred to as the "CD5 Methodology."

The Fund will seek to (i) provide large cap coverage of the digital asset market; (ii) minimize transaction costs through

low turnover of the Fund's portfolio; and (iii) create a portfolio that could be replicated through direct purchases in the Digital Asset Market. Because Index Components target the Large Cap Sector and are included in the CD5 in accordance with market capitalization and liquidity criteria, as of March 31, 2025, the CD5 covered approximately 86% of the market capitalization of the entire digital asset market, excluding stablecoins and meme coins, based on data provided by the Index Provider calculated using data from CoinMarketCap.com. Additionally, as of March 31, 2025, the CD5 covered approximately 84% of the market capitalization of the Index Universe.

The Fund Components will consist of the Index Components except that the Manager may determine to exclude a particular Index Component and/or rebalance the weighting of the Fund Components, in its discretion under certain rules-based circumstances. The weightings of each Fund Component (the "Weightings") are generally expected to be the same as the Index Weightings except when the Manager determines to exclude one or more digital assets from the Fund Components and/or rebalance the weighting of the Fund Components, in which case the Weightings are generally

expected to be calculated proportionally to the respective Index Weightings for the remaining Index Components. The Fund uses the CD5 Methodology, described further below, to construct its portfolio.

The Manager represents that it will ensure, on an initial and continuing basis, that, as of 4:00 p.m. E.T. on every trading day, at least 85% of the Fund Components consist of commodities that are the primary investment underlying ETPs previously approved by the Commission to list and trade on a national securities exchange (“Approved Components”) and that no more than 15% of the Fund Components will be non-Approved Components.³⁷ Specifically:

- To the extent the Fund’s composition is or is anticipated to be less than 85% Approved Components as of 4:00 p.m. E.T. on a given trading day,³⁸ the Manager will promptly notify the Exchange.

- In addition, as soon as practicable and in any event by no later than the

³⁷ The Exchange notes that this requirement is similar to Commentary .01(d)(1) to Rule 8.600–E regarding Managed Fund Shares, which permits portfolio holdings of series of Managed Fund Shares to be in listed derivatives provided that, in the aggregate, at least 90% of the weight of such holdings invested in futures, exchange-traded options, and listed swaps consist of, on both an initial and continued basis, futures, options, and swaps for which the Exchange may obtain information via the Intermarket Surveillance Group (“ISG”) from other members or affiliates of the ISG or for which the principal market is a market with which the Exchange has a comprehensive surveillance sharing agreement (“CSSA”). Here, the Exchange proposes that 85% of the Fund’s holdings consist of Approved Components. As of the date of this filing, the Commission has approved exchange-traded products based on spot Bitcoin and Ether in view of listing exchanges’ ability to obtain information via CSSA from the CME, a U.S. regulated market whose Bitcoin and Ether futures markets consistently have been highly correlated to spot Bitcoin and spot Ether, respectively, to assist in surveilling for fraudulent and manipulative acts and practices. See Bitcoin ETP Approval Order, note 43, *infra*; Ether ETP Approval Order, note 45, *infra*. The Exchange represents that its procedures are reasonably designed to surveil for fraudulent and manipulative acts and practices with respect to trading of the Fund’s Shares on the Exchange. In addition, the Exchange believes that the allocation structure proposed by the Manager mitigates certain risks with respect to trading of the Fund’s Shares because the Fund will be rebalanced if necessary, on a daily basis, to ensure that a majority of the Fund Components are Approved Components for which the Commission has found that there are sufficient means of preventing fraud and manipulation. The Manager notes that, as of the date of this filing, the Fund Components that meet this standard are Bitcoin and Ether, which currently make up approximately 80% and 11% of the Index, respectively.

³⁸ The Manager represents that it does not intend for the Fund Components to consist of less than 85% Approved Components intra-day or expect that the Fund Components will deviate from at least 85% Approved Components and will monitor the allocation of the Fund Components.

beginning of the NYSE Arca Core Trading Session on the following trading day, the Manager will rebalance the Fund’s portfolio according to the methodology described in the Fund’s prospectus (the “Prospectus”) such that at least 85% of the Weightings will consist of Approved Components.

- Moreover, if it is anticipated that, as of 4:00 p.m. E.T. on a given trading day, the Fund’s portfolio will not consist of at least 85% Approved Components by the start of the next NYSE Arca Core Trading Session, the Manager will notify the Exchange as soon as practicable (and, in any event, no later than 9:15 a.m. E.T.), and the Exchange will halt trading in the Fund Shares until at least 85% of the Weightings consist of Approved Components.

Eligibility and Weighting

Under the CD5 Methodology and subject to the below, a digital asset included in the Index Universe will generally be eligible for inclusion in the CD5 as an Index Component, and thus the Fund’s portfolio as a Fund Component, if it satisfies market capitalization, liquidity and data availability metrics determined by the Index Provider. Digital assets will be included in the CD5 on a market capitalization-weighted basis. For example, a digital asset with a larger market capitalization will have a higher representation in the CD5, and thus the Fund’s portfolio (unless the Manager excludes the digital asset from the Fund and/or rebalances the weighting of the Fund Components). Market capitalization refers to a digital asset’s market value, as determined by multiplying the number of tokens of such digital asset in circulation by the market price of a token of such digital asset. The market price per token of a Fund Component will be determined by reference to the applicable Index Price. The market capitalization of any digital assets not in the CD5, and therefore not held by the Fund, will be determined based on data that the Index Provider obtains directly from trading platforms and other service providers. Because the Fund creates Shares in exchange for Fund Components on a daily basis, the market capitalization of each Fund Component is calculated, and its Weighting therefore fluctuates, daily in accordance with changes in the market price of such Fund Components.

The CD5, and therefore the Fund, is rebalanced on a quarterly basis according to the CD5 Methodology during a period beginning 14 days before the last business day of each January, April, July, and October (each

such period, an “Index Rebalancing Period”).

Inclusion of New Fund Components

In order for a new digital asset to qualify for inclusion in the CD5, and thus the Fund’s portfolio during a Fund Rebalancing Period,³⁹ it must be included in the Index Universe and included in the CoinDesk 20 Index (the “Selection Universe”).

Inclusion in the Selection Universe

The digital assets that make up the Selection Universe are selected according to the following rules:

(1) All digital assets in the Index Universe are ranked by 90-day median daily value traded. Daily volume data is sourced from USD and USDC trading pairs aggregated across centralized Digital Asset Trading Platforms that contribute to the applicable Index Price;

(2) Following the ranking described in Step 1, the 50 highest ranked current constituents of the Index Universe and 40 highest ranked non-constituents of the Index Universe are eligible to qualify for the Selection Universe. The remainder of the assets are removed;

(3) Following removal of ineligible digital assets described in Step 2, all digital assets that are not supported by Coinbase Custody Trust Company are removed;

(4) Following the removals described in Step 3, the digital assets are ranked by market capitalization;

(5) Following the ranking described in Step 4, the top 15 ranked digital assets are selected for inclusion in the Selection Universe;

(6) From the remaining digital assets not selected in Step 5, any current constituents included within the top 25 ranking described in Step 4 are selected in order, until 20 digital assets are selected for inclusion in the Selection Universe;

(7) If Step 6 results in fewer than 20 constituents included in the Selection Universe, the highest-ranked non-constituents from the remaining digital assets are selected until 20 constituents are selected.

Inclusion in the CD5

In order for a digital asset in the Selection Universe to be included in the CD5 and therefore the Fund’s portfolio during a Fund Rebalancing Period, such digital asset must satisfy the following rules: (i) the top four assets by market capitalization in the Selection Universe will automatically be selected for

³⁹ A “Fund Rebalancing Period” is a period during which the Manager reviews for rebalancing the Fund’s portfolio in accordance with the policies and procedures set forth in the Prospectus.

inclusion; (ii) the fifth digital asset selected for inclusion will be a current CD5 constituent unless such digital asset falls below the top six digital asset by market capitalization in the Selection Universe; (iii) if no such current constituent is eligible pursuant to (ii), the digital asset with the largest market capitalization from the remaining Selection Universe will be selected for inclusion. Under ordinary circumstances, the CD5 is intended to have five digital asset constituents.

Outside of the quarterly Index Rebalancing Period, the Index Provider may remove a digital asset as an Index Component from the CD5 under extraordinary circumstances. For example, if an Index Component is determined to be a “security” under the federal securities laws by the Commission, a federal court or other U.S. government agency, it may be removed from the CD5 at a date determined and announced by the Index Provider. In the event the Index Provider removes an Index Component outside of the quarterly rebalancing period, the Manager expects the Fund would rebalance and the relevant digital asset would be removed as a Fund Component as soon as practical.

Index Components Compared to Fund Components

The Fund Components consist of the Index Components except when the Manager determines to exclude a particular Index Component in view of one or more of the following criteria (the “Exclusion Criteria”), as determined in the sole discretion of the Manager:

- none or few of the Authorized Participants or service providers has the ability to trade or otherwise support the digital asset;
- the Manager believes, based on current guidance, that use or trading of the digital asset raises or potentially raises significant governmental, policy or regulatory concerns or is subject or likely subject to a specialized regulatory regime, such as the U.S. federal securities or commodities laws or similar laws in other significant jurisdictions;⁴⁰

⁴⁰ The Manager will determine whether a particular digital asset that is included or eligible for inclusion in the Fund is a security for purposes of the federal securities laws by considering a number of factors, including the various definitions of “security” under the federal securities laws and federal court decisions interpreting elements of these definitions, such as the U.S. Supreme Court’s decisions in the *Howey* and *Reves* cases, as well as reports, orders, press releases, public statements and speeches by the Commission and its staff providing guidance on when a digital asset may be a security for purposes of the federal securities laws. The Manager does not intend to permit the

- the digital asset’s underlying code contains, or may contain, significant flaws or vulnerabilities; or

- there is limited or no reliable information regarding, or concerns over the intentions of, the core developers of the digital asset.

The Weightings are generally expected to be the same as the Index Weightings except when one or more digital assets have been excluded from the Fund Components based on the Exclusion Criteria, in which case the Weightings are generally expected to be calculated proportionally to the respective Index Weightings for the remaining Index Components.

The Manager may exclude a digital asset or rebalance the Weighting of an existing Fund Component to the extent its inclusion as a Fund Component or projected Weighting would exceed a threshold that could, in the Manager’s sole discretion, require the Fund to register as an investment company under the Investment Company Act, require the Manager to register as an investment adviser under the Investment Advisers Act, or conflict with any continued listing requirement (including that the Fund Components consist of 85% Approved Components as noted above).

The Manager will retain discretion to include or exclude individual digital assets from the Fund Components, or to rebalance Fund Components, only in certain rules-based circumstances, as described above. Accordingly, the Manager believes that the Fund will be in compliance with Rule 10A–3⁴¹ under the Act, as provided by NYSE Arca Rule 5.3–E.

Constituent Trading Platform Selection

According to the Prospectus, the Constituent Trading Platforms that are included in each Fund Component’s Index Price are selected by the Index Provider utilizing a methodology that is guided by the IOSCO principles for financial benchmarks. For a trading platform to become a Constituent Trading Platform, it must satisfy the Inclusion Criteria below:

- No evidence in the past 12 months of trading restrictions on individuals or entities that would otherwise meet the trading platform’s eligibility requirements to trade;

Fund to hold any digital asset that the Manager determines is a security under the federal securities laws, whether that determination is initially made by the Manager itself, or because a federal court upholds an allegation that a digital asset is a security.

⁴¹ With respect to the application of Rule 10A–3 (17 CFR 240.10A–3) under the Act, the Fund relies on the exemption contained in Rule 10A–3(c)(7).

- No evidence in the past 12 months of undisclosed restrictions on deposits or withdrawals from user accounts;

- Real-time price discovery;
- Limited or no capital controls;⁴²
- Transparent ownership including a publicly-known ownership entity;
- Publicly available language and policies addressing legal and regulatory compliance, including KYC, AML and other policies designed to comply with relevant regulations that might apply to it;

- Offer programmatic spot trading of the trading pair⁴³ and reliably publish trade prices and volumes on a real-time basis through Rest and Websocket APIs;

- Is a centralized spot trading platform ranked BB or higher in the Index Provider’s latest published Trading Platform Benchmark report; and
- Is not classified as an Excluded Trading Platform⁴⁴ as defined in the Index Provider’s Digital Asset Indices Policy Methodology.

All trading platforms that meet these Inclusion Criteria will be assigned to a “Trading Platform Category” as defined by the additional criteria below, and at least one Category 1 Trading Platform must be included in each Index Price.

- A “Category 1 Trading Platform” is a trading platform:
 - Licensed and/or able to serve investors, retail or professional, in the U.S.; and
 - That maintains sufficient USD or USDC liquidity relative to the size of the listed assets.
- A “Category 2 Trading Platform” is a trading platform:
 - Licensed (including in-principal licensure) and/or able to serve investors, retail or professional, in one or more of the following jurisdictions:
 - United Kingdom
 - European Union⁴⁵

⁴² “Capital controls” in this context means governmental sanctions that would limit the movement of capital into, or out of, the jurisdiction in which such Digital Asset Trading Platforms operate.

⁴³ Trading platforms with programmatic trading offer traders an application programming interface that permits trading by sending programmed commands to the trading platform.

⁴⁴ Certain Index Provider products support derivatives and other exchange-listed financial products that may require additional cooperation and support from contributing trading platforms. The Index Provider may designate one or more exchanges as an “Excluded Trading Platform” as it deems necessary or prudent to ensure adequate support. Excluded Trading Platforms will be ineligible to contribute to relevant Digital Asset Price Indices and Index Prices as specified in their respective methodologies.

⁴⁵ In the event a trading platform is only licensed or able to serve investors in select European Union countries and none of the other listed jurisdictions, the Index Provider reserves the right to evaluate its eligibility on a case-by-case basis.

- Hong Kong
- Singapore; and
- That maintains sufficient USD or USDC liquidity relative to the size of the listed assets.

A Digital Asset Trading Platform is removed as a Constituent Trading Platform when it no longer satisfies the Inclusion Criteria. The Index Provider does not currently include data from over-the-counter markets or derivatives platforms among the Constituent Trading Platforms. According to the Prospectus, over-the-counter data is not currently included because of the potential for trades to include a significant premium or discount paid for larger liquidity, which creates an uneven comparison relative to more active markets. There is also a higher potential for over-the-counter transactions to not be arms-length, and thus not be representative of a true market price.

The Index Provider and the Manager have entered into the Index License Agreement, governing the Manager's use of the Index Prices.⁴⁶ Pursuant to the terms of the Index License Agreement, the Index Provider may adjust the calculation methodology for an Index Price without notice to, or consent of, the Fund or its shareholders. The Index Provider may decide to change the calculation methodology to maintain the integrity of the Index Price calculation should it identify or become aware of previously unknown variables or issues with the existing methodology that it believes could materially impact its performance and/or reliability. The Index Provider has sole discretion over the determination of Index Prices and may change the methodologies for determining the Index Prices from time to time. Shareholders will be notified of any material changes to the calculation methodology or the Index Prices in the Fund's current reports and will be notified of all other changes that the Manager considers significant in the Fund's periodic or current reports. The Manager will determine the materiality of any changes to the Index Prices on a case-by-case basis, in consultation with external counsel.

The Index Provider may change the trading venues that are used to calculate the Index Prices or otherwise change the way in which an Index Price is calculated at any time. For example, the Index Provider has scheduled quarterly reviews in which it may add or remove Constituent Trading Platforms that

satisfy or fail the Inclusion Criteria. The Index Provider does not have any obligation to consider the interests of the Manager, the Fund, the shareholders, or anyone else in connection with such changes. While the Index Provider is not required to publicize or explain the changes or to alert the Manager to such changes, it has historically notified the Fund (and other subscribers to the Index) of any material changes to the Constituent Trading Platforms, including any additions or removals, contemporaneous with its issuance of press releases in connection with the same. The Manager will notify investors of any such material event by filing a current report on Form 8-K. Although the Index Price methodology is designed to operate without any manual intervention, rare events would justify manual intervention. Intervention of this kind would be in response to non-market-related events, such as the halting of deposits or withdrawals of funds on a Digital Asset Trading Platform, the unannounced closure of operations on a Digital Asset Trading Platform, insolvency or the compromise of user funds. In the event that such an intervention is necessary, the Index Provider would issue a public announcement through its website, API or other established communication channels with its clients.

Determination of the Index Prices

The Index Price, as reflected by the CoinDesk CCIXber Reference Rate, for each Fund Component is calculated through the application of an algorithm to the price of each Fund Component on the Constituent Trading Platforms calculated every 5 seconds over a 24-hour period. The Index Price's algorithm is expected to reflect a five-pronged methodology to calculate the Index Price from the Constituent Trading Platforms for each Fund Component:

- *Volume Weighting:* Constituent Trading Platforms with greater liquidity receive a higher weighting in each Index Price, increasing the ability to execute against (*i.e.*, replicate) the Index Price in the underlying spot markets. The Index Price methodology is a volume-weighted real-time price where each Constituent Trading Platform is weighted based on its trailing 24-hour volume.

- *FX Conversion:* Each Index Price algorithm utilizes a volume-weighted real-time FX conversion rate for any trading activity for the relevant Stablecoin-USD pair. This normalizes all trading activity to USD denomination.

- *Outlier Detection Factor:* Each Index Price algorithm excludes trade data and price(s) deemed to be an outlier relative to the most recently calculated Index Price.

- *Inactivity Adjustment:* Each Index Price algorithm penalizes stale activity from any given Constituent Trading Platform. When a Constituent Trading Platform does not have recent trading data, the outdated prices and their contribution to the Index Price calculation are gradually reduced until they are de-weighted to 0.1%. Similarly, once trading activity at a Constituent Trading Platform resumes, the corresponding weighting for that Constituent Trading Platform will no longer be penalized.

- *Manipulation Resistance:* In an effort to determine and prioritize the most significant Constituent Trading Platforms (*i.e.*, those that are likely to have the most impact on price discovery) for a given asset, the Index Provider conducts a Constituent Trading Platform selection and review process, which seeks to identify the highest-ranking Constituent Trading Platforms based on both qualitative and quantitative factors. The qualitative review includes legal and regulation, data provision, security, trade monitoring, market quality, and negative events policy, among others. The quantitative review includes review of trading activity for the asset on the given Constituent Trading Platform.

In addition, the Index Provider re-evaluates the weighting algorithm on a periodic basis, but maintains discretion to change the way in which an Index Price is calculated based on its periodic review or in extreme circumstances. Nonetheless, the Manager believes that each Index Price is designed to limit exposure to trading or price distortion of any individual Digital Asset Trading Platform that experiences periods of unusual activity or limited liquidity, and thereby mitigate the effects of potential manipulation by discounting, in real-time, anomalous price movements at individual Digital Asset Trading Platforms.

The Manager believes the Index Provider's selection process for Constituent Trading Platforms as well as the methodology of the Index Price's algorithm provides a more accurate picture of Fund Component price movements than a simple average of Digital Asset Trading Platform spot prices, and that the weighting of Fund Component prices on the Constituent Trading Platforms limits the inclusion of data that is influenced by temporary price dislocations that may result from technical problems, limited liquidity or

⁴⁶ Upon entering into the Index License Agreement, the Manager and the Index Provider terminated the license agreement between the parties dated as of February 28, 2019.

fraudulent activity elsewhere in the Fund Component spot market. By referencing multiple trading venues and weighting them based on trade activity, the Manager believes that the impact of any potential fraud, manipulation or anomalous trading activity occurring on any single venue is reduced.

If an Index Price becomes unavailable, or if the Manager determines in good faith that such Index Price does not reflect an accurate price for a Fund Component, then the Manager will, on a best efforts basis, contact the Index Provider to obtain such Index Price directly from the Index Provider. If after such contact such Index Price remains unavailable or the Manager continues to believe in good faith that such Index Price does not reflect an accurate price for the Fund Component, then the Manager will employ a cascading set of rules to determine the Index Price, as described below in “Determination of the Index Price When the Index Price is Unavailable.”

The Manager values the Fund Components for operational purposes by reference to the Index Prices. The Index Prices are used to calculate the value of each Fund Component as of 4:00 p.m., New York time, on each business day.

Illustrative Example

For the purposes of illustration, outlined below are examples of how the attributes that impact weighting and adjustments in the aforementioned methodology may be utilized to generate an Index Price for a digital asset. For example, Constituent Trading Platforms used to calculate the Index Price of the digital asset may include trading platforms such as Bitstamp, Kraken, LMAX Digital, and Crypto.com.

The Index Price algorithm, as described above, is designed to account for manipulation at the outset by only including data from executed trades on Constituent Trading Platforms. Then, the below-listed elements may impact the weighting of the Constituent Trading Platforms on the Index Price as follows:

- **Volume Weighting:** Each Constituent Trading Platform will be weighted to appropriately reflect the trading volume share of the Constituent Trading Platform relative to all the Constituent Trading Platforms during this same period. For example, an average hourly weighting of 67.06%, 14.57%, 11.88%, and 6.49% for Bitstamp, Kraken, LMAX Digital, and Crypto.com, respectively, would represent each Constituent Trading Platform's share of trading volume during the same period.

- **Inactivity Adjustment:** Assume that a Constituent Trading Platform

represented a 14% weighting on the Index Price of the digital asset, which is based on the per-second calculations of its trading volume and price-variance relative to the cohort of Constituent Trading Platforms included in such Index Price, and then went offline for approximately two hours. The Index Price algorithm would automatically recognize inactivity and start de-weighting the Constituent Trading Platform at the 5-minute mark and continue to do so with each additional 5-minute period of inactivity until its influence was effectively zero, 25 minutes after becoming inactive. As soon as trading activity resumed at the Constituent Trading Platform, the Index Price algorithm would re-weight it to the appropriate weighting based on trading volume and price-variance relative to the cohort of Constituent Trading Platforms included in the Index Price.

- **Price Outlier Detection:** New traded prices from Constituent Trading Platforms are compared to the latest calculated Index Price. If a new traded price deviates by $\pm 5\%$ from the latest calculated Index Price, it will be considered an outlier and will not be used in the calculation of the Index Price until such time as a majority of the Constituent Trading Platforms are similarly considered outlier prices. In that case, the new prices will be used to calculate the Index Price. For example, if the Index Price is \$10 and there is a new trade price of \$11 from Constituent Trading Platform X, the price of \$11 will be considered an outlier and will not be used. However, if the most recent prices on a majority of the Constituent Trading Platforms are aligned with the price of \$11, then these prices will no longer be considered outliers and will be used to calculate the new Index Price.

Determination of the Index Price When the Index Price is Unavailable

The Manager uses the following cascading set of rules to calculate the Index Price for a Fund Component when the Index Price for such Fund Component is unavailable. For the avoidance of doubt, the Manager will employ the below rules sequentially and in the order as presented below, should one or more specific rule(s) fail:

1. Index Price = The price set by the relevant Index Price as of 4:00 p.m., New York time, on the valuation date.⁴⁷ If the relevant Index Price becomes unavailable, or if the Manager determines in good faith that such Index

Price does not reflect an accurate digital asset price, then the Manager will, on a best efforts basis, contact the Index Provider to obtain the Index Price directly from the Index Provider. If after such contact such Index Price remains unavailable or the Manager continues to believe in good faith that such Index Price does not reflect an accurate price for the relevant digital asset, then the Manager will employ the next rule to determine the Index Price. There are no predefined criteria to make a good faith assessment and it will be made by the Manager in its sole discretion.

2. Index Price = The price set by Coin Metrics Real-Time Rate (the “Secondary Index”) as of 4:00 p.m., New York time, on the valuation date (the “Secondary Index Price”). The Secondary Index Price is a real-time reference rate price, calculated using trade data from constituent markets selected by Coin Metrics, Inc. (the “Secondary Index Provider”). The Secondary Index Price is calculated by applying weighted-median techniques to such trade data where half the weight is derived from the trading volume on each constituent market and half is derived from inverse price variance, where a constituent market with high price variance as a result of outliers or market anomalies compared to other constituent markets is assigned a smaller weight. The Secondary Index Provider and the Manager have entered into the master services agreement, dated as of August 4, 2020, and order forms thereunder, pursuant to which the Manager may obtain and use the Secondary Index and the Secondary Index Price from the Secondary Index Provider. If the Secondary Index Price for the relevant Fund Component becomes unavailable, or if the Manager determines in good faith that the Secondary Index Price does not reflect an accurate price for such Fund Component, then the Manager will, on a best efforts basis, contact the Secondary Index Provider to obtain the Secondary Index Price directly from the Secondary Index Provider. If after such contact the Secondary Index Price remains unavailable or the Manager continues to believe in good faith that the Secondary Index Price does not reflect an accurate price for such Fund Component, then the Manager will employ the next rule to determine the Digital Index Price. There are no predefined criteria to make a good faith assessment and it will be made by the Manager in its sole discretion.

3. Index Price = The price set by the Fund's principal market (as defined in the Prospectus) (the “Tertiary Pricing Option”) as of 4:00 p.m., New York

⁴⁷ The valuation date is any day for which the value of the Fund Components in the Fund may be calculated utilizing the Index Prices.

time, on the valuation date. The Tertiary Pricing Option is a spot price derived from the relevant principal market's public data feed that is believed to be consistently publishing pricing information as of 4:00 p.m., New York time, and is provided to the Manager via an application programming interface. If the Tertiary Pricing Option becomes unavailable, or if the Manager determines in good faith that the Tertiary Pricing Option does not reflect an accurate price for such Fund Component, then the Manager will, on a best efforts basis, contact the Tertiary Pricing Provider to obtain the Tertiary Pricing Option directly from the Tertiary Pricing Provider. If after such contact the Tertiary Pricing Option remains unavailable after such contact or the Manager continues to believe in good faith that the Tertiary Pricing Option does not reflect an accurate price for such Fund Component, then the Manager will employ the next rule to determine the Index Price. There are no predefined criteria to make a good faith assessment and it will be made by the Manager in its sole discretion.

4. Index Price = The Manager will use its best judgment to determine a good faith estimate of the Index Price. There are no predefined criteria to make a good faith assessment and it will be made by the Manager in its sole discretion.

In the event of a fork, the Index Provider may calculate the Index Price based on a digital asset that the Manager does not believe to be the appropriate asset that is held by the Fund (*i.e.*, a digital asset other than the Fund Components).⁴⁸ In this event, the Manager has full discretion to use a different index provider or calculate the Index Price itself using its best judgment. In such an event, the Exchange will submit a proposed rule filing to contemplate the assets that would subsequently be held by the Fund.

The Manager may, in its sole discretion, select a different index provider, select a different index price

provided by the Index Provider, calculate the Index Price by using the cascading set of rules set forth above, or change the cascading set of rules set forth above at any time.⁴⁹

The Structure and Operation of the Fund Protects Investors and Satisfies Commission Requirements for Digital Asset-Based Exchange Traded Products

On January 10, 2024, the Commission approved the listing and trading of shares of the Grayscale Bitcoin Trust (BTC) and Bitwise Bitcoin ETF under NYSE Arca Rule 8.201-E (Commodity-Based Trust Shares); the Hashdex Bitcoin ETF under NYSE Arca Rule 8.500-E (Trust Units); the iShares Bitcoin Trust and Valkyrie Bitcoin Fund under Nasdaq Rule 5711(d) (Commodity-Based Trust Shares); and the ARK 21Shares Bitcoin ETF, Invesco Galaxy Bitcoin ETF, VanEck Bitcoin Trust, the WisdomTree Bitcoin Fund, Fidelity Wise Origin Bitcoin Fund, and Franklin Bitcoin ETF under BZX Rule 14.11(e)(4) (Commodity-Based Trust Shares) (collectively, the "Bitcoin ETPs").⁵⁰ In the Bitcoin ETP Approval Order, the Commission found that the proposed rule changes to list the Bitcoin ETPs demonstrated that there were "sufficient 'other means' of preventing fraud and manipulation," including that:

[B]ased on the record before the Commission and the improved quality of the correlation analysis in the record, including the Commission's own analysis, the Commission is able to conclude that fraud or manipulation that impacts prices in spot bitcoin markets would likely similarly impact CME bitcoin futures prices. And because the CME's surveillance can assist in detecting those impacts on CME bitcoin futures prices, the Exchanges' comprehensive surveillance-sharing agreement with the CME—a U.S. regulated market whose bitcoin futures market is consistently highly correlated to spot bitcoin, albeit not of "significant size" related to spot bitcoin—can be reasonably expected to assist in surveilling for fraudulent and manipulative

acts and practices in the specific context of the [Bitcoin ETPs].⁵¹

Similarly, on May 23, 2024, the Commission approved the listing and trading of shares of the Grayscale Ethereum Trust and the Bitwise Ethereum ETF under NYSE Arca Rule 8.201-E (Commodity-Based Trust Shares); the iShares Ethereum Trust under Nasdaq Rule 5711(d) (Commodity-Based Trust Shares); and the VanEck Ethereum Trust, ARK 21Shares Ethereum ETF, Invesco Galaxy Ethereum ETF, Fidelity Ethereum Fund, and the Franklin Ethereum ETF under BZX Rule 14.11(e)(4) (Commodity-Based Trust Shares) (collectively, the "Ether ETPs").⁵² In the Ether ETP Approval Order, the Commission found that the proposed rule changes to list the Ether ETPs demonstrated that there were "sufficient 'other means' of preventing fraud and manipulation," including that:

[B]ased on the record before the Commission and the correlation analyses in the record, including the Commission's own analysis, the Commission is able to conclude that fraud or manipulation that impacts prices in spot ether markets would likely similarly impact CME ether futures prices. And because the CME's surveillance can assist in detecting those impacts on CME ether futures prices, the Exchanges' comprehensive surveillance-sharing agreement with the CME—a U.S.-regulated market whose ether futures market is consistently highly correlated to spot ether, albeit not of "significant size" related to spot ether—can be reasonably expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the [Ether ETPs].⁵³

The Fund is structured and will operate in a manner materially the same as the Bitcoin ETPs and Ether ETPs and the Fund Components currently primarily consist of Bitcoin and Ether, and at least 85% of the Fund Components will consist of Approved Components as described above. Accordingly, the Manager believes that, for the reasons set forth in the Bitcoin ETP Approval Order and Ether ETP Approval Order, listing and trading

⁴⁸ According to the Registration Statement, when a modification is introduced and a substantial majority of users and validators consent to the modification, the change is implemented and the network remains uninterrupted. However, if less than a substantial majority of users and validators consent to the proposed modification, and the modification is not compatible with the software prior to its modification, the consequence would be what is known as a "hard fork", with one group running the pre-modified software and the other running the modified software. The effect of such a fork would be the existence of two versions of a digital asset running in parallel, yet lacking interchangeability, such as in July 2016 when Ether "forked" into Ether and a new digital asset, Ether Classic.

⁴⁹ The Manager will provide notice of any such changes in the Fund's periodic or current reports and, if the Manager makes such a change other than on an ad hoc or temporary basis, the Exchange will file a proposed rule change with the Commission.

⁵⁰ Securities Exchange Act Release No. 99306 (January 10, 2024), 89 FR 3008 (January 17, 2024) (SR-NYSEARCA-2021-90; SR-NYSEARCA-2023-44; SR-NYSEARCA-2023-58; SR-NASDAQ-2023-016; SR-NASDAQ-2023-019; SR-CboeBZX-2023028; SR-CboeBZX-2023-038; SR-CboeBZX-2023-040; SR-CboeBZX-2023-042; SRCboeBZX-2023-044; SR-CboeBZX-2023-072) (Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, to List and Trade Bitcoin-Based Commodity-Based Trust Shares and Trust Units) (the "Bitcoin ETP Approval Order").

⁵¹ Bitcoin ETP Approval Order, 89 FR at 3009-11.

⁵² Securities Exchange Act Release No. 100224 (May 23, 2024), 89 FR 46937 (May 30, 2024) (SR-NYSEARCA-2023-70; SR-NYSEARCA-2024-31; SRNASDAQ-2023-045; SR-CboeBZX-2023-069; SR-CboeBZX-2023-070; SR-CboeBZX-2023-087; SR-CboeBZX-2023-095; SR-CboeBZX-2024-018) (Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, to List and Trade Shares of Ether-Based Exchange-Traded Products) (the "Ether ETP Approval Order").

⁵³ Ether ETP Approval Order, 89 FR at 46941.

Shares of the Fund would be consistent with the requirements of the Act.⁵⁴

The Manager acknowledges that the Fund Components include minority positions in digital assets that are not Bitcoin or Ether (e.g., SOL, XRP, and ADA), but believes that, given that the Fund will be rebalanced, if necessary, so that, on a daily basis, Approved Components will comprise at least 85% of the Fund Components at the start of every NYSE Arca Core Trading Session, listing and trading Shares of the Fund would be consistent with the requirements of the Act. Nonetheless, for purposes of the Fund's proposal, the Manager anticipates that the Commission may have certain concerns about the Fund's non-Bitcoin and Ether assets, as articulated in prior spot digital asset ETP proposal disapproval orders,⁵⁵ and addresses each of these in turn below.

In the Prior Spot Digital Asset ETP Disapproval Orders, the Commission outlined that a proposal relating to a digital asset-based ETP could satisfy its concerns regarding potential for fraud and manipulation by demonstrating:

(1) *Inherent Resistance to Fraud and Manipulation*: that the underlying commodity market is inherently resistant to fraud and manipulation;

(2) *Other Means to Prevent Fraud and Manipulation*: that there are other means to prevent fraudulent and manipulative acts and practices that are sufficient; or

(3) *Surveillance Sharing*: that the listing exchange has entered into a surveillance sharing agreement with a regulated market of significant size relating to the underlying or reference assets.

As described below, the Manager believes the structure and operation of the Fund are designed to prevent fraudulent and manipulative acts and practices, to protect investors and the public interest, and to respond to concerns that the Commission may have with respect to potential fraud and manipulation in the context of a digital asset-based ETP.

How the Fund Meets Standards in the Prior Spot Digital Asset ETP Disapproval Orders

1. Resistance to or Prevention of Fraud and Manipulation

In the Prior Spot Digital Asset ETP Disapproval Orders, the Commission disagreed with the proposition that a digital asset's fungibility, transportability and exchange tradability combine to provide unique protections against, and allow such digital asset to be uniquely resistant to, attempts at price manipulation. The Commission reached its conclusion based on concessions by one issuer that 95% of the reported trading in the digital asset, Bitcoin, is "fake" or non-economic, effectively admitting that the properties of Bitcoin do not make it inherently resistant to manipulation. Such issuer's concessions were further compounded by evidence of potential and actual fraud and manipulation in the historical trading of Bitcoin on certain marketplaces such as (1) "wash" trading, (2) trading based on material, non-public information, including the dissemination of false and misleading information, (3) manipulative activity involving Tether, and (4) fraud and manipulation.⁵⁶

The Manager acknowledges the possibility that fraud and manipulation may exist in commodity markets and that digital asset trading, such as certain of the Fund Components, *on any given trading platform* may be no more uniquely resistant to fraud and manipulation than other commodity markets.⁵⁷ However, the Manager believes that the fundamental features of digital assets, including fungibility, transportability and exchange tradability offer novel protections beyond those that exist in traditional commodity markets or equity markets when combined with other means, as discussed further below.

2. Other Means To Prevent Fraud and Manipulation

The Commission has recognized that a listing exchange could demonstrate that other means to prevent fraudulent and manipulative acts and practices are sufficient to justify dispensing with the requisite surveillance-sharing agreement.⁵⁸ In evaluating the effectiveness of this type of resistance, the Commission does not apply a "cannot be manipulated" standard. Instead, the Commission requires that such resistance to fraud and manipulation be novel and beyond those protections that exist in traditional commodity markets or equity markets for which the Commission has long required surveillance-sharing agreements in the context of listing derivative securities products.⁵⁹

The Manager believes the Fund's use of the Index Prices represents a novel means to prevent fraud and manipulation from impacting a reference price for the Fund Components and that it offers protections beyond those that exist in traditional commodity markets or equity markets. Specifically, digital assets, such as the Fund Components, are novel and exist outside traditional commodity markets. It therefore stands to reason that the methods by which they trade will be novel and that the market for digital assets like the Fund Components will have different attributes than traditional commodity markets. Digital assets like the Fund Components were only introduced within the past decade, twenty years after the first U.S.

potential types of manipulation in the Bitcoin spot market). The Commission has also noted that fraud and manipulation in the Bitcoin spot market could persist for a significant duration. *See, e.g.,* Bitwise Order, 84 FR at 55405 & n.379.

⁵⁷ *See generally* Bitwise Order.

⁵⁸ *See* Winklevoss Order, 84 FR at 37580, 37582–91; Bitwise Order, 84 FR at 55383, 55385–406; Wilshire Phoenix Order, 85 FR at 12597.

⁵⁹ *See* Winklevoss Order, 84 FR at 37582; Wilshire Phoenix Order, 85 FR at 12597.

⁵⁴ In particular, Grayscale Bitcoin Trust (BTC) ("GBTC") and Grayscale Ethereum Trust (ETH) ("ETHE"), affiliates of the Fund that are structured substantially similarly to the Fund, currently list their shares on the Exchange under NYSE Arca Rule 8.201–E. The Fund will have the same service providers as GBTC and ETHE.

⁵⁵ *See* Securities Exchange Act Release Nos. 83723 (July 26, 2018), 83 FR 37579 (August 1, 2018) (SR–BatsBZX–2016–30) (Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, To List and Trade Shares of the Winklevoss Bitcoin Fund) (the "Winklevoss Order"); 87267 (October 9, 2019), 84 FR 55382 (October 16, 2019) (SR–NYSEArca–2019–01) (Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, Relating to the Listing and Trading of Shares of the Bitwise Bitcoin ETF Fund Under NYSE Arca Rule 8.201–E) (the "Bitwise Order"); 88284 (February 26, 2020), 85 FR 12595 (March 3, 2020) (SR–NYSEArca–2019–39) (Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) and to List and Trade Shares of the United States Bitcoin and Treasury Investment Trust Under NYSE Arca Rule 8.201–E) (the "Wilshire Phoenix Order"); 83904 (August 22, 2018), 83 FR 43934 (August 28, 2018) (SR–NYSEArca–2017–139) (Order Disapproving a Proposed Rule Change to List and Trade the Shares of the ProShares Bitcoin ETF and the ProShares Short Bitcoin ETF) (the "ProShares Order"); 83912 (August 22, 2018), 83 FR 43912 (August 28, 2018) (SR–NYSEArca–2018–02) (Order Disapproving a Proposed Rule Change Relating to Listing and Trading of the Direxion Daily Bitcoin Bear 1X Shares, Direxion Daily Bitcoin 1.25X Bull Shares, Direxion Daily Bitcoin 1.5X Bull Shares, Direxion Daily Bitcoin 2X Bull Shares Under NYSE Arca Rule 8.201–E) (the "Direxion Order"); 83913 (August 22, 2018), 83 FR 43923 (August 28, 2018) (SR–CboeBZX–2018–01) (Order Disapproving a Proposed Rule Change to List and Trade the Shares of the GraniteShares Bitcoin ETF and the GraniteShares Short Bitcoin ETF) (the "GraniteShares Order") (together, the "Prior Spot Digital Asset ETP Disapproval Orders").

⁵⁶ *See* Bitwise Order, 84 FR at 55383 (discussing analysis of the Bitcoin spot market that asserts that 95% of the spot market is dominated by fake and non-economic activity, such as wash trades), 55391 (discussing possible sources of fraud and manipulation in the bitcoin spot market). *See also* Winklevoss Order, 83 FR at 37585–86 (discussing pending litigation against a Bitcoin trading platform for fraudulent conduct relating to Tether); Bitwise Order, 84 FR at 55391 n.140, 55402 & n.331 (same); Winklevoss Order, 83 FR at 37584–86 (discussing

exchange-traded funds (“ETFs”) were offered⁶⁰ and 150 years after the first futures were offered.⁶¹ In contrast to other commodities such as gold, silver, platinum, palladium or copper, which the Commission has noted all had at least one significant, regulated market for trading futures on the underlying commodity at the time commodity trust ETPs were approved for listing and trading, the first trading in digital assets like the Fund Components took place entirely in an open, transparent and online setting where other commodities cannot trade.

The Manager believes the Fund’s use of the Index Prices specifically addresses the Commission’s concerns in that they serve as an alternative means to prevent fraud and manipulation. Specifically, the Manager believes that the Index Prices can (i) mitigate the effects of fraud, manipulation and other anomalous trading activity on the Fund Components’ reference rates, (ii) provide a real-time, volume-weighted fair value of the Fund Components and (iii) appropriately handle and adjust for non-market related events.

As described in more detail below, the Manager believes that the use of the Index Prices accomplishes those objectives in the following ways:

1. The Index Prices track the Digital Asset Trading Platform Market price through trading activity at Constituent Trading Platforms, which are made up of “U.S.-Regulated Trading Platforms” and Digital Asset Trading Platforms licensed (including in-principal licensure) and/or able to serve retail or professional investors in one or more of the United Kingdom, European Union, Hong Kong and Singapore;⁶²

2. The Index Prices are designed to mitigate the impact of instances of fraud, manipulation and other

anomalous trading activity in real-time through systematic adjustments;

3. The Index Prices are constructed and maintained by an expert third-party index provider, allowing for prudent handling of non-market-related events; and

4. The Index Prices are designed to mitigate the impact of instances of fraud, manipulation and other anomalous trading activity concentrated on any one specific trading platform through a cross-trading platform composite reference rate over a 60-minute period.

1. *The Index Prices track the Digital Asset Trading Platform Market price through trading activity at Constituent Trading Platforms, which are made up of “U.S.-Regulated Trading Platforms” and Digital Asset Trading Platforms licensed (including in-principal licensure) and/or able to serve retail or professional investors in one or more of the United Kingdom, European Union, Hong Kong, and Singapore.*

The Index Prices maintain a minimum number of three trading platforms to track the Digital Asset Trading Platform Market while offering replicability for traders and market makers.⁶³

U.S.-Regulated Trading Platforms possess safeguards that help to protect against fraud and manipulation. For example, U.S.-Regulated Trading Platforms regulated by the NYDFS under the BitLicense program are required to implement measures designed to effectively detect, prevent, and respond to fraud, attempted fraud, market manipulation, and similar wrongdoing, and to monitor, control, investigate and report back to the NYDFS regarding any wrongdoing.⁶⁴ These trading platforms also have the following obligations:⁶⁵

- Submission of audited financial statements including income

statements, statements of assets/liabilities, insurance, and banking;

- Compliance with capitalization requirements set at NYDFS’s discretion;

- Prohibitions against the sale or encumbrance to protect full reserves of custodian assets;

- Fingerprints and photographs of employees with access to customer funds;

- Retention of a qualified Chief Information Security Officer and annual penetration testing/audits;

- Documented business continuity and disaster recovery plan, independently tested annually; and

- Participation in an independent exam by NYDFS.

Furthermore, all U.S.-Regulated Trading Platforms are considered MSBs that are subject to FinCEN’s federal and state reporting requirements that provide additional safeguards. For example, unscrupulous traders may be less likely to engage in fraudulent or manipulative acts and practices on trading platforms that (1) report suspicious activity to FinCEN as money services businesses, (2) report to state regulators as money transmitters, and/or (3) require customer identification through KYC procedures. U.S.-Regulated Trading Platforms are required to:⁶⁶

- Identify people with ownership stakes or controlling roles in the MSB;

- Establish a formal Anti-Money Laundering (AML) policy in place with documentation, training, independent review, and a named compliance officer;

- Implement strict customer identification and verification policies and procedures;

- File Suspicious Activity Reports (SARs) for suspicious customer transactions;

- File Currency Transaction Reports (CTRs) for cash-in or cash-out transactions greater than \$10,000; and

- Maintain a five-year record of currency exchanges greater than \$1,000 and money transfers greater than \$3,000.

Lastly, pursuant to its view that Bitcoin and Ether are commodities, the CFTC has authority to police fraud and manipulation on U.S.-Regulated Trading Platforms that trade those digital assets.⁶⁷

⁶⁰ SEC, “Investor Bulletin: Exchange-Traded Funds (ETFs),” August 2012, <https://www.sec.gov/investor/alerts/etfs.pdf>.

⁶¹ Commodity Futures Trading Commission (“CFTC”), “History of the CFTC,” https://www.cftc.gov/About/HistoryoftheCFTC/history_precftc.html.

⁶² “U.S.-Regulated Trading Platforms” are trading platforms in the Digital Asset Trading Platform Market required to comply with applicable U.S. federal and state licensing requirements and practices regarding AML and KYC regulations. Constituent Trading Platforms are U.S.-Regulated Trading Platforms or Digital Asset Trading Platforms licensed and/or able to serve investors in the United Kingdom, European Union, Hong Kong and/or Singapore. As of the date of this filing, the U.S.-Regulated Trading Platforms that the Index Provider considered for inclusion in the Index Prices were Bitstamp, Crypto.com, Gemini, itBit, LMAX Digital, and Kraken. From these trading platforms, the Index Provider then applies additional Inclusion Criteria to determine the Constituent Trading Platforms.

⁶³ According to the Manager, the more trading platforms included in the Index Price, the more ability there is for traders and market makers to trade against the Index Price by arbitraging price differences. For example, in the event of variances between Fund Component prices on Constituent Trading Platforms and non-Constituent Trading Platforms, arbitrage trading opportunities would exist. These discrepancies generally consolidate over time, as price differences across trading platforms are realized and capitalized upon by traders and market makers.

⁶⁴ See, e.g., “DFS Takes Action to Deter Fraud and Manipulation in Virtual Currency Markets,” available at: <https://www.dfs.ny.gov/about/press/pr1802071.htm>. As of the date of this filing, two of the Constituent Trading Platforms, Bitstamp and itBit, are regulated by NYDFS.

⁶⁵ See “New York’s Final “BitLicense” Rule: Overview and Changes from July 2014 Proposal,” June 5, 2015, Davis Polk, available at: https://www.davispolk.com/files/new_yorks_final_bitlicense_rule_overview_changes_july_2014_proposal.pdf.

⁶⁶ See BSA Requirements for MSBs, FinCEN website: <https://www.fincen.gov/bsarequirements-msbs>.

⁶⁷ “U.S. CFTC Chief Behnam Reinforces View of Ether as Commodity,” CoinDesk (Mar. 28, 2023), <https://www.coindesk.com/policy/2023/03/28/us-cftc-chief-behnam-reinforces-view-of-ether-as-commodity/>; CME Group, https://www.cmegroup.com/markets/cryptocurrencies/ether/ether.html?gad=1&gclid=EAIaIQobChMI44KBmu7ygAMVavvBx2P4g5yEAAASAAEgJSZfD_BwE&gclid=aw.ds.

The non-U.S.-Regulated Trading Platforms included in the Index Prices are licensed (including in-principal licensure) and/or are able to serve retail or professional investors in one or more of the following jurisdictions: United Kingdom, European Union, Hong Kong, and Singapore, which are jurisdictions that meet the criteria set forth below. When reviewing non-U.S.-Regulated Trading Platforms for eligibility in certain indices and reference rates, the Index Provider evaluates criteria regarding such Digital Asset Trading Platforms, including but not limited to:

- Whether the Digital Asset Trading Platform has a dedicated virtual asset regulator;
- Whether such a regulator is overseen by, and receives a mandate from, the primary markets regulator in the Digital Asset Trading Platform jurisdiction; and
- Whether the Digital Asset Trading Platform produces sufficient trading volume to meaningfully contribute to accurate price discovery within the index or reference rate.

These criteria are not an exhaustive list of the Index Provider's considerations when evaluating a non-U.S.-Regulated Trading Platform, and the Index Provider may adjust these criteria from time to time.

2. *The Index Prices are designed to mitigate the impact of instances of fraud, manipulation, and other anomalous trading activity in real-time through systematic adjustments.*

The Index Prices are calculated once every second according to a systematic methodology that relies on observed trading activity on the Constituent Trading Platforms. While the precise methodology underlying each Index Price is currently proprietary, the key elements of the Index Prices are outlined below:

- *Volume Weighting:* Constituent Trading Platforms with greater liquidity receive a higher weighting in the Index Prices, increasing the ability to execute against (*i.e.*, replicate) the Index Prices in the underlying spot markets. The Index Price methodology is a volume-weighted real-time price where each Constituent Trading Platform is weighted based on its trailing 24-hour volume.

- *FX Conversion:* The Index Price algorithm utilizes a volume-weighted real-time FX conversion rate for any trading activity for the relevant Stablecoin-USD pair. This normalizes all trading activity to USD denomination.

- *Outlier Detection Factor:* The Index Price algorithm excludes trade data and price(s) deemed to be an outlier relative

to the most recently calculated Index Price.

- *Inactivity Adjustment:* The Index Price algorithm penalizes stale activity from any given Constituent Trading Platform. When a Constituent Trading Platform does not have recent trading data, the outdated prices and their contribution to the Index Price calculation are gradually reduced until they are de-weighted to 0.1%. Similarly, once trading activity at a Constituent Trading Platform resumes, the corresponding weighting for that Constituent Trading Platform will no longer be penalized.

- *Manipulation Resistance:* In an effort to determine and prioritize the most significant Constituent Trading Platforms (*i.e.*, those that are likely to have the most impact on price discovery) for a given asset, the Index Price utilizes a Constituent Trading Platform selection and review process, which seeks to identify the highest-ranking Constituent Trading Platforms based on both qualitative and quantitative factors. The qualitative review includes legal and regulation, data provision, security, trade monitoring, market quality, and negative events policy, among others. The quantitative review includes review of trading activity for the asset on the given Constituent Trading Platform.

In addition, the Index Provider re-evaluates the weighting algorithm on a periodic basis, but maintains discretion to change the way in which an Index Price is calculated based on its periodic review or in extreme circumstances. Nonetheless, the Manager believes that each Index Price is designed to limit exposure to trading or price distortion of any individual Digital Asset Trading Platform that experiences periods of unusual activity or limited liquidity, and thereby mitigate the effects of potential manipulation by discounting, in real-time, anomalous price movements at individual Digital Asset Trading Platforms.

The Manager believes the Index Provider's selection process for Constituent Trading Platforms as well as the methodology of the Index Price's algorithm provides a more accurate picture of Fund Component price movements than a simple average of Digital Asset Trading Platform spot prices, and that the weighting of Fund Component prices on the Constituent Trading Platforms limits the inclusion of data that is influenced by temporary price dislocations that may result from technical problems, limited liquidity or fraudulent activity elsewhere in the Fund Component spot market. By referencing multiple trading venues and

weighting them based on trade activity, the Manager believes that the impact of any potential fraud, manipulation or anomalous trading activity occurring on any single venue is reduced.

3. *The Index Prices are constructed and maintained by an expert third-party index provider, allowing for prudent handling of non-market-related events.*

The Index Provider reviews and periodically updates which trading platforms are included in the Index Prices by utilizing methodologies guided by the IOSCO principles for financial benchmarks.

According to the Index Provider's methodology for each Index Price, for a trading platform to become a Constituent Trading Platform, it must satisfy the following Inclusion Criteria:

- No evidence in the past 12 months of trading restrictions on individuals or entities that would otherwise meet the trading platform's eligibility requirements to trade;
- No evidence in the past 12 months of undisclosed restrictions on deposits or withdrawals from user accounts;
- Real-time price discovery;
- Limited or no capital controls;
- Transparent ownership including a publicly-known ownership entity;
- Publicly available language and policies addressing legal and regulatory compliance, including KYC, AML and other policies designed to comply with relevant regulations that might apply to it;
- Offer programmatic spot trading of the trading pair and reliably publish trade prices and volumes on a real-time basis through Rest and Websocket APIs;
- Is a centralized spot trading platform ranked BB or higher in the Index Provider's latest published Trading Platform Benchmark report; and
- Is not classified as an Excluded Trading Platform as defined in the Index Provider's Digital Asset Indices Policy Methodology.

All trading platforms that meet these Inclusion Criteria will be assigned to a Trading Platform Category as defined by the additional criteria below, and at least one Category 1 Trading Platform must be included in each Index Price.

- A "Category 1 Trading Platform" is a trading platform:
 - Licensed and/or able to serve investors, retail or professional, in the U.S.; and
 - That maintains sufficient USD or USDC liquidity relative to the size of the listed assets.
- A "Category 2 Trading Platform" is a trading platform:
 - Licensed (including in-principal licensure) and/or able to serve investors, retail or professional, in one or more of the following jurisdictions:

- United Kingdom
- European Union
- Hong Kong
- Singapore; and
- That maintain a sufficient USD or USDC liquidity relative to the size of the listed assets.

Although the Index Provider's methodology is designed to operate without any human interference, rare events would justify manual intervention. Manual intervention would only be in response to "non-market-related events" (e.g., halting of deposits or withdrawals of funds, unannounced closure of trading platform operations, insolvency, compromise of user funds, etc.). In the event that such an intervention is necessary, the Index Provider would issue a public announcement through its website, API and other established communication channels with its clients.⁶⁸

4. The Index Prices are designed to mitigate the impact of instances of fraud, manipulation and other anomalous trading activity concentrated on any one specific trading platform through a cross-trading platform composite index rate.

The Index Prices are based on the price and volume data of multiple Constituent Trading Platforms that satisfy the Index Provider's Inclusion Criteria. The Manager believes that, by referencing multiple trading venues and weighting them based on trade activity, the impact of any potential fraud, manipulation, or anomalous trading activity occurring on any single venue is reduced. Specifically, the effects of fraud, manipulation, or anomalous trading activity occurring on any single venue are de-weighted and consequently diluted by non-anomalous trading activity from other Constituent Trading Platforms.

Although each Index Price is designed to accurately capture the market price of the digital asset it tracks, third parties may be able to purchase and sell such digital assets on public or private markets not included among the constituent Digital Asset Trading Platforms of such Index Price, and such transactions may take place at prices materially higher or lower than the Index Price. Moreover, there may be variances in the prices of digital assets on the various Digital Asset Trading Platforms, including as a result of differences in fee structures or administrative procedures on different Digital Asset Trading Platforms.

For example, based on Index Price data provided by the Index Provider, on any given day during the twelve months ended March 31, 2025, the maximum differential between the 4:00 p.m., New York time spot price of Bitcoin on any single Digital Asset Trading Platform included in the Index Price was 0.84% and the average of the maximum differentials of the 4:00 p.m., New York time spot price of each Digital Asset Trading Platform included in the Index Price and the Index Price was 0.33%. During this same period, the average differential between the 4:00 p.m., New York time spot prices of all the Digital Asset Trading Platforms included in the Index Price and the Index Price was 0.01%. Further, based on CD5 data provided by the Index Provider, on any given day during the twelve months ended March 31, 2025, the maximum differential between the 4:00 p.m., New York time spot price of Ether on any single Digital Asset Trading Platform included in the Index Price and the Index Price was 1.88% and the average of the maximum differentials of the 4:00 p.m., New York time spot price of each Digital Asset Trading Platform included in the Index Price and the Index Price was 0.47%. During this same period, the average differential between the 4:00 p.m., New York time spot prices of all the Digital Asset Trading Platforms included in the Index Price and the Index Price was 0.004%. All Digital Asset Trading Platforms that were included in the relevant Index Price throughout the period were considered in this analysis.

The Fund will price its Shares at 4:00 p.m., New York time based on the Index Prices. While the pricing on the Digital Asset Trading Platforms that contribute to the Index Prices is known to the market, the Manager believes that, even if efforts to manipulate the price of the Fund Components at 4:00 p.m. E.T. were successful on a Digital Asset Trading Platform, the effect of such activity on the pricing of the Fund would be mitigated due to the controls embedded in the structure of the Index Prices.

Accordingly, the Manager believes that the Index Prices have the ability to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity on the Fund Components reference rates, (ii) provide a real-time, volume-weighted fair value of the Fund Components and (iii) appropriately handle and adjust for non-market related events.

Creation and Redemption of Shares

Authorized Participants may submit orders to create or redeem Shares under procedures for "Cash Orders."

The Authorized Participants will deliver only cash to create Shares and will receive only cash when redeeming Shares. Further, Authorized Participants will not directly or indirectly purchase, hold, deliver, or receive the Fund Components as part of the creation or redemption process or otherwise direct the Fund or a third party with respect to purchasing, holding, delivering, or receiving the Fund Components as part of the creation or redemption process.

The Fund will create Shares by receiving the Fund Components from a third party that is not the Authorized Participant and the Fund, or an affiliate of the Fund (and in any event not the Authorized Participant), is responsible for selecting the third party to deliver the Fund Components. Further, the third party will not be acting as an agent of the Authorized Participant with respect to the delivery of the Fund Components to the Fund or acting at the direction of the Authorized Participant with respect to the delivery of the Fund Components to the Fund. The Fund will redeem Shares by delivering the Fund Components to a third party that is not the Authorized Participant and the Fund, or an affiliate of the Fund (and in any event not the Authorized Participant), is responsible for selecting the third party to receive the Fund Components. Further, the third party will not be acting as an agent of the Authorized Participant with respect to the receipt of the Fund Components from the Fund or acting at the direction of the Authorized Participant with respect to the receipt of the Fund Components from the Fund.

Cash Orders are made through the participation of a Liquidity Provider⁶⁹

⁶⁹ A "Liquidity Provider" means one or more eligible companies that facilitate the purchase and sale of the Fund Components in connection with creations or redemptions pursuant to Cash Orders. The Liquidity Providers with which Grayscale Investments Sponsors, LLC, acting other than in its capacity as the Manager (in such other capacity, the "Liquidity Engager") will engage in Fund Component transactions are third parties that are not affiliated with the Manager or the Fund and are not acting as agents of the Fund, the Manager, or any Authorized Participant, and all transactions will be done on an arms-length basis. Except for the contractual relationships between each Liquidity Provider and Grayscale Investments Sponsors, LLC in its capacity as the Liquidity Engager, there is no contractual relationship between each Liquidity Provider and the Fund, the Manager, or any Authorized Participant. When seeking to buy Fund Components in connection with creations or sell Fund Components in connection with redemptions, the Liquidity Engager will seek to obtain commercially reasonable prices and terms from the

Continued

⁶⁸ To the extent any such intervention has a material impact on the Fund, the Manager will also issue a public announcement.

who obtains or receives the Fund Components in exchange for cash, and are facilitated by the Transfer Agent and Grayscale Investments Sponsors, LLC, acting in its capacity as the Liquidity Engager. Liquidity Providers are not party to the Participant Agreements (as defined below) and are engaged separately by the Liquidity Engager.

According to the Registration Statement, the Fund creates Baskets (as described below) of Shares only upon receipt of the Fund Components and redeems Shares only by distributing the Fund Components. “Authorized Participants” are the only persons that may place orders to create and redeem Baskets. Each Authorized Participant must (i) be a registered broker-dealer and (ii) enter into an agreement with the Manager and Transfer Agent that provides the procedures for the creation and redemption of Baskets and for the delivery of the Fund Components required for the creation and redemption of Baskets via a Liquidity Provider (each, a “Participant Agreement”). An Authorized Participant may act for its own account or as agent for broker-dealers, custodians and other securities market participants that wish to create or redeem Baskets. Shareholders who are not Authorized Participants will only be able to create or redeem their Shares through an Authorized Participant.

The Fund issues Shares to and redeems Shares from Authorized Participants on an ongoing basis, but only in one or more “Baskets” (with a Basket being a block of 10,000 Shares). The Fund will not issue fractions of a Basket.

The creation and redemption of Baskets will be made only in exchange for the delivery to the Fund, or the distribution by the Fund, of the amount of whole and fractional tokens of each Fund Component represented by each Basket being created or redeemed, which is determined by dividing (x) the total amount of tokens of each Fund Component owned by the Fund at 4:00 p.m., New York time, on the trade date of a creation or redemption order, after deducting the amount of each Fund Component representing the U.S. dollar value of accrued but unpaid fees and expenses of the Fund (converted using the Index Prices at such time, and carried to the eighth decimal place), by (y) the number of Shares outstanding at such time (with the quotient so obtained calculated to one one-hundred-millionth of the Fund Components (*i.e.*,

carried to the eighth decimal place)), and multiplying such quotient by 10,000 (for each Fund Component, the Fund Component Basket Amount). The sum of the Fund Component Basket Amounts for all Fund Components then held by the Fund, and the Cash Portion,⁷⁰ if any, together comprise the “Basket Amount.” The U.S. dollar value of a Basket is equal to the sum of (x) each Fund Component Basket Amount multiplied by the applicable Index Price and (y) the Cash Portion, if any (the “Basket NAV”). The Basket NAV multiplied by the number of Baskets being created or redeemed is referred to as the “Total Basket NAV.” All questions as to the calculation of the Basket Amount will be conclusively determined by the Manager and will be final and binding on all persons interested in the Fund. The amount of Fund Components represented by a Share will gradually decrease over time as the Fund Components are used to pay the Fund’s expenses. Each Share represented approximately 0.0004 of one Bitcoin, 0.0022 of one Ether, 0.0094 of one SOL, 0.6584 of one ADA, and 1.0640 of one XRP as of June 20, 2025.⁷¹

The Basket Amount multiplied by the number of Baskets being created or redeemed is the “Total Basket Amount.” The creation of Baskets requires the delivery to the Fund of the Total Basket Amount and the redemption of Baskets requires the distribution by the Fund of the Total Basket Amount.

Although the Fund creates Baskets only upon the receipt of the Fund Components, and redeems Baskets only by distributing the Fund Components, an Authorized Participant will submit Cash Orders, pursuant to which the Authorized Participant will deposit cash with, or accept cash from, the Transfer Agent in connection with the creation and redemption of Baskets.

Cash Orders will be facilitated by the Transfer Agent and Liquidity Engager, acting other than in its capacity as Manager. On an order-by-order basis, the Liquidity Engager will engage one or more Liquidity Providers to obtain or receive the Fund Components in exchange for cash in connection with such order, as described in more detail below.

⁷⁰ “Cash Portion” means for any trade date, the amount of U.S. dollars determined by dividing (x) the amount of U.S. dollars or other fiat currency (as converted into U.S. dollars at the applicable exchange rate as of 4:00 p.m., New York time) held by the Fund at 4:00 p.m., New York time, on such trade date by (y) the number of Shares outstanding at such time (with the quotient so obtained calculated to one one-hundred-millionth), and multiplying such quotient by 100.

⁷¹ Calculated as if the Fund were operating based on the CD5.

Unless the Manager requires that a Cash Order be effected at actual execution prices (an “Actual Execution Cash Order”),⁷² each Authorized Participant that submits a Cash Order to create or redeem Baskets (a “Variable Fee Cash Order”)⁷³ will pay a fee (the “Variable Fee”) based on the Total Basket NAV, and any price differential of the Fund Components between the trade date and the settlement date will be borne solely by the Liquidity Provider until such Fund Components have been received or liquidated by the Fund. The Variable Fee is intended to cover all of a Liquidity Provider’s expenses in connection with the creation or redemption order, including any trading platform fees that the Liquidity Provider incurs in connection with buying or selling the Fund Components. The amount may be changed by the Manager in its sole discretion at any time, and Liquidity Providers will communicate to the Manager in advance the Variable Fee they would be willing to accept in connection with a Variable Fee Cash Order, based on market conditions and other factors existing at the time of such Variable Fee Cash Order.

Alternatively, the Manager may require that a Cash Order be effected as an Actual Execution Cash Order, in its sole discretion based on market conditions and other factors existing at the time of such Cash Order, and under such circumstances, any price differential of the Fund Components

⁷² With respect to a creation or redemption pursuant to an Actual Execution Cash Order, as between the Fund and an Authorized Participant, the Authorized Participant is responsible for the dollar cost of the difference between the Fund Components’ price utilized in calculating Total Basket NAV on the trade date and the price at which the Fund acquires or disposes of the Fund Components on the settlement date. If the price realized in acquiring or disposing of the corresponding Total Basket Amount is higher than the Total Basket NAV, the Authorized Participant will bear the dollar cost of such difference, in the case of a creation, by delivering cash in the amount of such shortfall (the “Additional Creation Cash”) to the Cash Account or, in the case of a redemption, with the amount of cash to be delivered to the Authorized Participant being reduced by the amount of such difference (the “Redemption Cash Shortfall”). If the price realized in acquiring the corresponding Total Basket Amount is lower than the Total Basket NAV, the Authorized Participant will benefit from such difference, with the Fund promptly returning cash in the amount of such excess (the “Excess Creation Cash”) to the Authorized Participant.

⁷³ Unless the Manager determines otherwise in its sole discretion based on market conditions and other factors existing at the time of such Cash Order, all creations and redemptions pursuant to Cash Orders are expected to be executed as Variable Fee Cash Orders, and any price differential of Fund Components between the trade date and the settlement date will be borne solely by the Liquidity Provider until such Fund Components have been received by the Fund.

approved Liquidity Providers. Once agreed upon, the transaction will generally occur on an “over-the-counter” basis.

between the trade date and the settlement date will be borne solely by the Authorized Participant until such Fund Components have been received or liquidated by the Fund.

In the case of creations, to transfer the Total Basket Amount to the Fund's Digital Asset Account, the Liquidity Provider will transfer the Fund Components to one of the public key addresses associated with the Digital Asset Account and as provided by the Manager. In the case of redemptions, the same procedure is conducted, but in reverse, using the public key addresses associated with the wallet of the Liquidity Provider and as provided by such party. All such transactions will be conducted on the blockchain and parties acknowledge and agree that such transfers may be irreversible if done incorrectly.

Authorized Participants do not pay a transaction fee to the Fund in connection with the creation or redemption of Baskets, but there may be transaction fees associated with the validation of the transfer of the Fund Components by the online, end-user-to-end-user network hosting a public transaction ledger, known as a Blockchain, and the source code comprising the basis for the

cryptographic and algorithmic protocols governing such network, which will be paid by the Custodian in the case of redemptions and the Authorized Participant or the Liquidity Provider in the case of creations. Service providers may charge Authorized Participants administrative fees for order placement and other services related to creation of Baskets. As discussed above, Authorized Participants will also pay the Variable Fee in connection with Variable Fee Cash Orders. Under certain circumstances Authorized Participants may also be required to deposit additional cash in the Cash Account, or be entitled to receive excess cash from the Cash Account, in connection with creations and redemptions pursuant to Actual Execution Cash Orders. Authorized Participants will receive no fees, commissions or other form of compensation or inducement of any kind from either the Manager or the Fund and no such person has any obligation or responsibility to the Manager or the Fund to effect any sale or resale of Shares.

Creation Procedures

On any business day, an Authorized Participant may place an order with the

Transfer Agent to create one or more Baskets.

Cash Orders for creation must be placed with the Transfer Agent no later than 1:59:59 p.m., New York time.

The Manager may in its sole discretion limit the number of Shares created pursuant to Cash Orders on any specified day without notice to the Authorized Participants and may direct the Marketing Agent to reject any Cash Orders in excess of such capped amount. In exercising its discretion to limit the number of Shares created pursuant to Cash Orders, the Manager expects to take into consideration a number of factors, including the availability of Liquidity Providers to facilitate Cash Orders and the cost of processing Cash Orders.

Creations under Cash Orders will take place as follows, where "T" is the trade date and each day in the sequence must be a business day. Before a creation order is placed, the Manager determines if such creation order will be a Variable Fee Cash Order or an Actual Execution Cash Order, which determination is communicated to the Authorized Participant.

Trade date (T)	Settlement date (T+1, or T+2, as established at the time of order placement)
- The Authorized Participant places a creation order with the Transfer Agent. - The Marketing Agent accepts (or rejects) the creation order, which is communicated to the Authorized Participant by the Transfer Agent. - The Manager notifies the Liquidity Provider of the creation order. - The Manager determines the Total Basket NAV and any Variable Fee and Additional Creation Cash as soon as practicable after 4:00 p.m., New York time.	- The Authorized Participant delivers to the Cash Account: * (x) in the case of a Variable Fee Cash Order, the Total Basket NAV, plus any Variable Fee; or (y) in the case of an Actual Execution Cash Order, the Total Basket NAV, plus any Additional Creation Cash, less any Excess Creation Cash, if applicable (such amount, as applicable, the "Required Creation Cash"). - The Liquidity Provider transfers the Total Basket Amount to the Fund's Digital Asset Account. - Once the Fund is in simultaneous possession of (x) the Total Basket Amount and (y) the Required Creation Cash, the Fund issues the aggregate number of Shares corresponding to the Baskets ordered by the Authorized Participant, which the Transfer Agent holds for the benefit of the Authorized Participant. - Cash equal to the Required Creation Cash is delivered to the Liquidity Provider from the Cash Account. - The Transfer Agent delivers Shares to the Authorized Participant by crediting the number of Baskets created to the Authorized Participant's DTC account.

*The "Cash Account" means the account maintained by the Transfer Agent for purposes of receiving cash from, and distributing cash to, Authorized Participants in connection with creations and redemptions pursuant to Cash Orders. For the avoidance of doubt, the Fund shall have no interest (beneficial, equitable or otherwise) in the Cash Account or any cash held therein.

Redemption Procedures

The procedures by which an Authorized Participant can redeem one or more Baskets mirror the procedures for the creation of Baskets. On any business day, an Authorized Participant may place a redemption order specifying the number of Baskets to be redeemed.

The redemption of Shares pursuant to Cash Orders will only take place if approved by the Manager in writing, in its sole discretion and on a case-by-case basis. In exercising its discretion to approve the redemption of Shares pursuant to Cash Orders, the Manager expects to take into consideration a number of factors, including the availability of Liquidity Providers to

facilitate Cash Orders and the cost of processing Cash Orders.

Cash Orders for redemption must be placed no later than 1:59:59 p.m., New York time on each business day. The Authorized Participants may only redeem Baskets and cannot redeem any Shares in an amount less than a Basket.

Redemptions under Cash Orders will take place as follows, where "T" is the

trade date and each day in the sequence must be a business day. Before a redemption order is placed, the Manager determines if such redemption order will be a Variable Fee Cash Order or an Actual Execution Cash Order, which determination is communicated to the Authorized Participant.

Trade date (T)	Settlement date (T+1 (or T+2 on case-by-case basis, as approved by Manager))
• The Authorized Participant places a redemption order with the Transfer Agent. • The Marketing Agent accepts (or rejects) the redemption order, which is communicated to the Authorized Participant by the Transfer Agent. • The Manager notifies the Liquidity Provider of the redemption order. • The Manager determines the Total Basket NAV and, in the case of a Variable Fee Cash Order, any Variable Fee, as soon as practicable after 4:00 p.m., New York time.	• The Authorized Participant delivers Baskets to be redeemed from its DTC account to the Transfer Agent. • The Liquidity Provider delivers to the Cash Account: (x) in the case of a Variable Fee Cash Order, the Total Basket NAV less any Variable Fee; or (y) in the case of an Actual Execution Cash Order, the actual proceeds to the Fund from the liquidation of the Total Basket Amount (such amount, as applicable, the "Required Redemption Cash"). • Once the Fund is in simultaneous possession of (x) the Total Basket Amount and (y) the Required Redemption Cash, the Transfer Agent cancels the Shares comprising the number of Baskets redeemed by the Authorized Participant. • The Custodian sends the Liquidity Provider the Total Basket Amount, and cash equal to the Required Redemption Cash is delivered to the Authorized Participant from the Cash Account.

Suspension or Rejection of Orders and Total Basket Amount

The creation or redemption of Shares may be suspended generally,⁷⁴ or refused with respect to particular requested creations or redemptions, during any period when the transfer books of the Transfer Agent are closed or if circumstances outside the control of the Manager or its delegates make it for all practicable purposes not feasible to process creation orders or redemption orders or for any other reason at any time or from time to time.⁷⁵ The Transfer Agent may reject an order or, after accepting an order, may cancel such order if: (i) such order is not presented in proper form as described in the Participant Agreement, (ii) the transfer of the Total Basket Amount comes from an account other than a wallet address that is known to the Custodian as belonging to a Liquidity Provider or (iii) the fulfillment of the order, in the opinion of counsel, might be unlawful, among other reasons. None of the Manager or its delegates will be liable for the suspension, rejection or

acceptance of any creation order or redemption order.

Availability of Information

The Fund's website (<https://www.grayscale.com/funds/grayscale-digital-large-cap-fund?public>), which will be publicly available at no charge, will include quantitative information on a per Share basis updated on a daily basis, including, (i) the current NAV per Share daily and the prior business day's NAV per Share and the reported closing price of the Shares; (ii) the mid-point of the bid-ask price⁷⁶ as of the time the NAV per Share is calculated ("Bid-Ask Price") and a calculation of the premium or discount of such price against such NAV per Share; and (iii) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid-Ask Price against the NAV per Share, within appropriate ranges, for each of the four previous calendar quarters (or for as long as the Fund has been trading as an ETP if shorter). In addition, on each business day the Fund's website will provide pricing information for the Shares and disclose the Fund Components, including: (i) the name of each Fund Component; (ii) the quantity of each Fund Component; and (iii) the weighting of each Fund Component. The Fund's website will also include a form of the prospectus for the Fund that may be downloaded.

One or more major market data vendors will provide the Intra-Day Fund Value ("IFV") per Share updated every 15 seconds, as calculated by the

Exchange or a third party financial data provider during the Exchange's Core Trading Session (9:30 a.m. to 4:00 p.m., E.T.).⁷⁷ The IFV will be calculated using the same methodology as the NAV per Share of the Fund (as described above), specifically by using the prior day's closing NAV per Share as a base and updating that value during the NYSE Arca Core Trading Session based on the Index Prices to reflect changes in the value of the Fund's NAV during the trading day.

The IFV disseminated during the NYSE Arca Core Trading Session should not be viewed as an actual real-time update of the NAV per Share, which will be calculated only once at the end of each trading day. The IFV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session by one or more major market data vendors. In addition, the IFV will be available through on-line information services.

The value of the Index Prices will be calculated or available on at least a 15-second delayed basis through major market data vendors. The Index, as well as additional information regarding the Index such as the Index Components and CD5 Methodology, is publicly available on a continuous basis on the Index Provider's website.

The NAV for the Fund will be calculated by the Manager once a day and will be disseminated daily to all market participants at the same time. To the extent that the Manager has utilized the cascading set of rules described in "Determination of the Index Prices"

⁷⁴ The Manager will notify the Exchange in the event that the creation or redemption of Shares will be suspended generally and will follow the Exchange's "Immediate Release Policy."

⁷⁵ Extenuating circumstances outside of the control of the Manager and its delegates or that could cause the transfer books of the Transfer Agent to be closed are outlined in the Participant Agreement and include, for example, public service or utility problems, power outages resulting in telephone, telecopy and computer failures, acts of God such as fires, floods or extreme weather conditions, market conditions or activities causing trading halts, systems failures involving computer or other information systems, including any failures or outages of the respective networks on which the Fund Components operate, affecting the Authorized Participant, the Manager, the Fund, the Transfer Agent, the Marketing Agent and the Custodian and similar extraordinary events.

⁷⁶ The bid-ask price of the Fund is determined using the highest bid and lowest offer on the Consolidated Tape as of the time of calculation of the closing day NAV.

⁷⁷ The IFV on a per Share basis disseminated during the NYSE Arca Core Trading Session should not be viewed as a real-time update of the NAV, which is calculated once a day.

above, the Fund's website will note the valuation methodology used and the price per Fund Components resulting from such calculation. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association ("CTA").

Quotation and last sale information for the Fund Components will be widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters. In addition, real-time price (and volume) data for the Fund Components is available by subscription from Reuters and Bloomberg. The spot price of the Fund Components is available on a 24-hour basis from major market data vendors, including Bloomberg and Reuters. Information relating to trading, including price and volume information, will be available from major market data vendors and from the trading platforms on which the Fund Components are traded. The normal trading hours for Digital Asset Trading Platforms are 24-hours per day, 365-days per year.

On each business day, the Manager will publish the Index Prices, the Fund's NAV, and the NAV per Share on the Fund's website as soon as practicable after its determination. If the NAV and NAV per Share have been calculated using a price per Fund Components other than the Index Price, the publication on the Fund's website will note the valuation methodology used and the price per Fund Components resulting from such calculation.

The Fund will provide website disclosure of its NAV daily. The website disclosure of the Fund's NAV will occur at the same time as the disclosure by the Manager of the NAV to Authorized Participants so that all market participants are provided such portfolio information at the same time. Therefore, the same portfolio information will be provided on the public website as well as in electronic files provided to Authorized Participants. Accordingly, each investor will have access to the current NAV of the Fund through the Fund's website, as well as from one or more major market data vendors.

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services.

Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4:00 a.m. to 8:00 p.m., E.T. in accordance with NYSE Arca Rule 7.34-E (Early, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Rule 7.6-E, the minimum price variation ("MPV") for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is \$0.01, with the exception of securities that are priced less than \$1.00, for which the MPV for order entry is \$0.0001.

The Shares will be required to conform to the initial and continued listing criteria under NYSE Arca Rule 8.500-E. The trading of the Shares will be subject to NYSE Arca Rule 8.500-E(f), which sets forth certain restrictions on Equity Trading Permit Holders ("ETP Holders") acting as registered Market Makers in Trust Units to facilitate surveillance. The Exchange represents that, for initial and continued listing, the Fund will be required to comply with Rule 10A-3⁷⁸ under the Act, as provided by NYSE Arca Rule 5.3-E. A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.⁷⁹ Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12-E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

The Exchange may halt trading during the day if it becomes aware that there has been an interruption to the dissemination of the IFV or the value of the Index Prices occurs. If the interruption to the dissemination of the IFV or the value of the Index Prices persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the NYSE Arca Core Trading Session on the trading day following the interruption. In addition, if the Exchange becomes

aware that the NAV per Share is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV per Share is available to all market participants.

Surveillance

The Exchange represents that trading in the Shares of the Fund will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by the Financial Industry Regulatory Authority ("FINRA") on behalf of the Exchange, which are designed to detect potential violations of Exchange rules and applicable federal securities laws with respect to the Shares of the Fund trading on the Exchange.⁸⁰ The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws with respect to the Shares of the Fund trading on the Exchange.

The existing surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity with respect to the Shares of the Fund. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate regarding trading in the Shares with other markets and other entities that are members of the ISG. The Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares and Fund Component derivatives from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and Fund Component derivatives from markets and other entities with which the Exchange has in place a CSSA.⁸¹ The Exchange is also

⁸⁰ FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

⁸¹ For a list of the current members of ISG, see www.isgportal.org. The Exchange notes that not all Fund Components may trade on markets that are members of ISG or with which the Exchange has in place a CSSA, but that, consistent with this proposed rule change, at least 85% of the Fund Components will consist of Approved Components as detailed above.

⁷⁸ 17 CFR 240.10A-3.

⁷⁹ See NYSE Arca Rule 7.12-E.

able to obtain information from ETP Holders acting as registered Market Makers regarding their trading (as principal or agent) in the Shares and any underlying Fund Components, options on Fund Components, or any other Fund Component derivatives.

In addition, under Rule 8.500–E(f), an ETP Holder acting as a registered Market Maker in the Shares is required to provide the Exchange with information relating to its accounts for trading in any underlying commodity, related futures or options on futures, or any other related derivatives. Commentary .04 of NYSE Arca Rule 11.3–E requires an ETP Holder acting as a registered Market Maker, and its affiliates, in the Shares to establish, maintain and enforce written policies and procedures reasonably designed to prevent the misuse of any material nonpublic information with respect to such products, any components of the related products, any physical asset or commodity underlying the product, applicable currencies, underlying indexes, related futures or options on futures, and any related derivative instruments (including the Shares). As a general matter, the Exchange has regulatory jurisdiction over its ETP Holders and their associated persons, which include any person or entity controlling an ETP Holder. To the extent the Exchange may be found to lack jurisdiction over a subsidiary or affiliate of an ETP Holder that does business only in commodities or futures contracts and that subsidiary or affiliate is a member of another regulatory organization, the Exchange could obtain information regarding the activities of such subsidiary or affiliate through surveillance sharing agreements with regulatory organizations to the extent the Exchange has such an agreement with that regulatory organization.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (a) the description of the index or portfolio or reference asset, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares on the Exchange.

The Manager has represented to the Exchange that it will advise the Exchange if the Fund ceases to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the

continued listing requirements. If the Exchange becomes aware that the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

Information Bulletin

At or prior to the commencement of trading, the Exchange will inform its ETP Holders in an “Information Bulletin” of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (1) the procedures for creations of Shares in Baskets; (2) NYSE Arca Rule 9.2–E(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) information regarding how the NAV and the IFV are disseminated; (4) the possibility that trading spreads and the resulting premium or discount on the Shares may widen during the Opening and Late Trading Sessions, when an updated IFV will not be calculated or publicly disseminated; (5) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information. The Exchange notes that investors purchasing Shares directly from the Fund will receive a prospectus.

In addition, the Information Bulletin will reference that the Fund is subject to various fees and expenses as described in the Registration Statement. The Information Bulletin will disclose that information about the Shares of the Fund is publicly available on the Fund’s website.

The Information Bulletin will also discuss any relief, if granted, by the Commission or the staff from any rules under the Act.

5. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁸² in general, and furthers the objectives of Section 6(b)(5) of the Act,⁸³ in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes the proposed changes to Rule 8.500–E would promote

just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because they would expand the universe of issuers that could issue Trust Units, thereby facilitating the listing and trading of additional series of Trust Units. The proposed changes to Rule 8.500–E would also promote clarity and specificity in the Exchange’s rules, including with respect to the permissible holdings underlying series of Trust Units. The Exchange believes the proposed change could promote competition by supporting the availability of additional exchange-traded products, to the benefit of all market participants. Except for the changes described above, all other requirements of Rule 8.500–E remain unchanged and would continue to apply to Trust Units listed and traded on the Exchange.

The Exchange also believes that the proposed addition of Trust Units to the enumerated derivative and special purpose securities that are subject to the provisions of Rule 5.3–E (Corporate Governance and Disclosure Policies) and Rule 5.3–E(e) (Shareholder/Annual Meetings) would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system by holding Trust Units to the same requirements currently applicable to other similar derivative and special purpose securities such as those listed pursuant to Rule 8.201–E.

With respect to the proposed listing and trading of Shares of the Fund, the Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Rule 8.500–E, as amended in this filing. The Exchange further believes that the proposed allocation of Fund Components to include at least 85% Approved Components, as described above, would remove impediments to and perfect the mechanism of a free and open market and a national market system because, at the start of each NYSE Arca Core Trading Session, at least 85% of the Fund Components will consist of Approved Components for which the Commission has found that there are sufficient means of preventing fraud and manipulation. The Exchange has in place certain surveillance procedures that are adequate to properly monitor trading in the Shares on the

⁸² 15 U.S.C. 78f(b).

⁸³ 15 U.S.C. 78f(b)(5).

Exchange in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws applicable to the Shares of the Fund trading on the Exchange. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares and Fund Component derivatives from such markets. In addition, the Exchange may obtain information regarding trading in the Shares and Fund Component derivatives from markets with which the Exchange has in place a CSSA. Also, pursuant to NYSE Arca Rule 8.500–E(f), the Exchange is able to obtain information from ETP Holders regarding their trading (as principal or agent) in the Shares and any underlying Fund Components, options on Fund Components, or any Fund Component derivatives.

The proposed rule change to list and trade Shares of the Fund is also designed to prevent fraudulent and manipulative acts and practices because the Index Prices (1) track the Digital Asset Trading Platform Market price through trading activity at Constituent Trading Platforms, which are made up of U.S.-Regulated Trading Platforms and/or Digital Asset Trading Platforms licensed and/or able to serve investors in the United Kingdom, European Union, Hong Kong and/or Singapore; (2) are designed to mitigate the impact of instances of fraud, manipulation and other anomalous trading activity in real-time through systematic adjustments; (3) are constructed and maintained by an expert third-party index provider, allowing for prudent handling of non-market-related events; and (4) are designed to mitigate the impact of instances of fraud, manipulation and other anomalous trading activity concentrated on any one specific trading platform through a cross-trading platform composite index rate. The Index Prices are designed to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity from impacting the Fund Components' reference rates, (ii) provide a real-time, volume-weighted fair value of the Fund Components and (iii) appropriately handle and adjust for non-market related events. The proposed rule change is also designed to prevent fraudulent and manipulative acts and practices because the Exchange is able to obtain information from the CME in regard to trading in futures on certain

Fund Components to assist in detecting and deterring potential fraud or manipulation with respect to certain Fund Components.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that there is a considerable amount of price and market information available on public websites and through professional and subscription services for the Fund Components. Investors may obtain, on a 24-hour basis, Fund Component pricing information based on the spot price for the Fund Components from various financial information service providers. The closing price and settlement prices of the Fund Components are readily available from the Digital Asset Trading Platforms and other publicly available websites. In addition, such prices are published in public sources, or on-line information services such as Bloomberg and Reuters. The NAV per Share will be calculated daily and made available to all market participants at the same time. The Fund will provide website disclosure of its NAV daily. One or more major market data vendors will disseminate for the Fund on a daily basis information with respect to the most recent NAV per Share and Shares outstanding. In addition, if the Exchange becomes aware that the NAV per Share is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. The IFV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session (normally 9:30 a.m., E.T., to 4:00 p.m., E.T.) by one or more major market data vendors. The Exchange represents that the Exchange may halt trading during the day in which an interruption to the dissemination of the IFV or the value of the Index Prices occurs. If the interruption to the dissemination of the IFV or the value of the Index Prices persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the NYSE Arca Core Trading Session on the trading day following the interruption.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace.

As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares on the Exchange and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a CSSA. In addition, as noted above, investors will have ready access to information regarding the Fund's NAV, IFV, and quotation and last sale information for the Shares.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional type of exchange-traded product which will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR–NYSEARCA–2024–87 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2024–87. 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–NYSEARCA–2024–87 and should be submitted on or before July 23, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸⁴

Sherry R. Haywood,
Assistant Secretary.
[FR Doc. 2025–12304 Filed 7–1–25; 8:45 am]
BILLING CODE 8011–01–P

**SECURITIES AND EXCHANGE
COMMISSION**

**[Release No. 34–103339; File No. SR–
NASDAQ–2025–045]**

**Self-Regulatory Organizations; The
Nasdaq Stock Market LLC; Notice of
Filing and Immediate Effectiveness of
Proposed Rule Change To Amend The
Nasdaq Options Market LLC (“NOM”)
Rules at Options 7, Section 2, Nasdaq
Options Market—Fees and Rebates**

June 27, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on June 16, 2025, The Nasdaq Stock Market LLC (“Nasdaq” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization’s
Statement of the Terms of Substance of
the Proposed Rule Change**

The Exchange proposes to amend The Nasdaq Options Market LLC (“NOM”) Rules at Options 7, Section 2, Nasdaq Options Market—Fees and Rebates. Specifically, NOM proposes to (1) increase the rebate for adding liquidity in penny symbols by NOM Market Makers³ and remove the corresponding note 11 incentive (2) increase the applicable monthly percentage volume

for Participants⁴ to achieve Tier 5 status, and (3) amend the note 6 incentive for Participants.
The text of the proposed rule change is available on the Exchange’s website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

**II. Self-Regulatory Organization’s
Statement of the Purpose of, and
Statutory Basis for, the Proposed Rule
Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization’s
Statement of the Purpose of, and
Statutory Basis for, the Proposed Rule
Change*

1. Purpose

The Exchange proposes to amend NOM’s Pricing Schedule at Options 7, Section 2, Nasdaq Options Market—Fees and Rebates.

Background

Today, NOM assesses certain fees and rebates for execution of contracts on NOM as follows:

REBATES TO ADD LIQUIDITY IN PENNY SYMBOLS

	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6
Customer	(\$0.20)	(\$0.25)	(\$0.43)	(\$0.44)	(\$0.45)	(\$0.48)
Professional	(0.20)	(0.25)	(0.43)	(0.44)	(0.45)	(0.47)
Broker-Dealer	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)
Firm	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)
Non-NOM Market Maker	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)
NOM Market Maker	(0.20)	(0.25)	(0.30)	(0.32)	(0.44)	(0.48)

⁸⁴ 17 CFR 200.30–3(a)(12).
¹ 15 U.S.C. 78s(b)(1).
² 17 CFR 240.19b–4.
³ The term “NOM Market Maker” or (“M”) is a Participant that has registered as a Market Maker on NOM pursuant to Options 2, Section 1, and must

also remain in good standing pursuant to Options 2, Section 9. In order to receive NOM Market Maker pricing in all securities, the Participant must be registered as a NOM Market Maker in at least one security. *See* Options 7, Section 1(a).
⁴ The term “Options Participant” or “Participant” mean a firm, or organization that is registered with

the Exchange pursuant to Options 2A of the NOM Rules for purposes of participating in options trading on NOM as a “Nasdaq Options Order Entry Firm” or “Nasdaq Options Market Maker”. *See* Options 1, Section 1(39).

FEES AND REBATES TO ADD LIQUIDITY
IN NON-PENNY SYMBOLS

Customer	(\$0.80)
Professional	(0.80)
Broker-Dealer	0.45
Firm	0.45
Non-NOM Market Maker	0.45
NOM Market Maker	0.35/\$0.00/ (\$0.20)/ (\$0.40)

FEES TO REMOVE LIQUIDITY IN PENNY
AND NON-PENNY SYMBOLS

	Penny symbols	Non-penny symbols
Customer	\$0.49	\$0.85
Professional	0.49	0.85
Broker-Dealer	0.50	1.25
Firm	0.50	1.25
Non-NOM Mar- ket Maker	0.50	1.25
NOM Market Maker	0.50	1.25

Further, Customer⁵ and Professional⁶ Rebates to Add Liquidity in Penny Symbols are paid per the highest tier achieved below. To determine the applicable percentage of total industry customer equity and ETF option average daily volume, unless otherwise stated, the Participant's Penny Symbol and Non-Penny Symbol Customer and/or Professional volume that adds liquidity will be included.

MONTHLY VOLUME

Tier 1	Participant adds Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Symbols and/or Non-Penny Symbols of up to 0.10% of total industry customer equity and ETF option average daily volume ("ADV") contracts per day in a month.
Tier 2	Participant adds Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Symbols and/or Non-Penny Symbols above 0.10% of total industry customer equity and ETF option ADV contracts per day in a month.
Tier 3	Participant: (a) adds Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Symbols and/or Non-Penny Symbols above 0.20% of total industry customer equity and ETF option ADV contracts per day in a month; or (b) adds Customer and/or Professional liquidity in Penny Symbols and/or Non-Penny Symbols above 0.05% of total industry customer equity and ETF option ADV contracts per day in a month and qualifies for MARS.
Tier 4	Participant adds Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Symbols and/or Non-Penny Symbols above 0.30% of total industry customer equity and ETF option ADV contracts per day in a month.
Tier 5	Participant adds Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Symbols and/or Non-Penny Symbols above 0.40% of total industry customer equity and ETF option ADV contracts per day in a month.
Tier 6	Participant adds Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Symbols and/or Non-Penny Symbols above 0.70% or more of total industry customer equity and ETF option ADV contracts per day in a month, or Participant: (1) adds Customer and/or Professional liquidity in Penny Symbols and/or Non-Penny Symbols of 0.10% or more of total industry customer equity and ETF option ADV contracts per day in a month, and (2) has added liquidity in all securities through one or more of its Nasdaq Market Center MPIDs that represent 1.00% or more of Consolidated Volume in a month or qualifies for MARS (defined below).

Finally, NOM Market Makers Rebates to Add Liquidity in Penny Symbols are

paid per the highest tier achieved based on the below 6 tiers.⁷

MONTHLY VOLUME

Tier 1	Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of up to 0.10% of total industry customer equity and ETF option average daily volume ("ADV") contracts per day in a month.
Tier 2	Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 0.10% of total industry customer equity and ETF option ADV contracts per day in a month.
Tier 3	Participant: (a) adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 0.20% of total industry customer equity and ETF option ADV contracts per day in a month; or (b)(1) adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 0.15% of total industry customer equity and ETF option ADV contracts per day in a month, (2) transacts in all securities through one or more of its Nasdaq Market Center MPIDs that represent (i) 0.50% or more of Consolidated Volume ("CV") which adds liquidity in the same month on The Nasdaq Stock Market or (ii) 50 million shares or more ADV which adds liquidity in the same month on The Nasdaq Stock Market, and (3) executes 1.5 million shares or more ADV in the same month utilizing the M-ELO order type on The Nasdaq Stock Market.
Tier 4	Participant adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.60% of total industry customer equity and ETF option ADV contracts per day in a month.
Tier 5	Participant: (a) adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 1.00% of total industry customer equity and ETF option ADV contracts per day in a month; or (b) adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.40% of total industry customer equity and ETF option ADV contracts per day in a month and transacts in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.40% or more of Consolidated Volume ("CV") which adds liquidity in the same month on The Nasdaq Stock Market.

⁵ The term "Customer" or ("C") applies to any transaction that is identified by a Participant for clearing in the Customer range at The Options Clearing Corporation ("OCC") which is not for the account of broker or dealer or for the account of a "Professional" (as that term is defined in Options 1, Section 1(a)(47)). See Options 7, Section 1(a).

⁶ The term "Professional" or ("P") means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s) pursuant to Options 1, Section 1(a)(47). All Professional orders

shall be appropriately marked by Participants. See Options 7, Section 1(a).

⁷ "Total Volume" is defined as Customer, Professional, Firm, Broker-Dealer, Non-NOM Market Maker and NOM Market Maker volume in Penny Symbols and/or Non-Penny Symbols which either adds or removes liquidity on NOM.

MONTHLY VOLUME—Continued

Tier 6	Participant: (a)(1) adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 0.95% of total industry customer equity and ETF option ADV contracts per day in a month, (2) executes Total Volume of 250,000 or more contracts per day in a month, of which 30,000 or more contracts per day in a month must be removing liquidity, and (3) adds Firm, Broker-Dealer and Non-NOM Market Maker liquidity in Non-Penny Symbols of 10,000 or more contracts per day in a month; or (b)(1) adds NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 1.40% of total industry customer equity and ETF option ADV contracts per day in a month, and (2) executes Total Volume of 250,000 or more contracts per day in a month, of which 15,000 or more contracts per day in a month must be removing liquidity.

Proposal

First, NOM proposes to increase the rebate for adding liquidity in penny symbols by NOM Market Makers from \$0.44 to \$0.46 and remove the corresponding note 11 incentive, which states that “NOM Participants that qualify for the Tier 5(b) NOM Market Maker Rebate to Add Liquidity in Penny Symbols and add NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of above 0.50% of total industry customer equity and ETF option ADV contracts per day in a month, will receive a \$0.46 per contract rebate to add liquidity in Penny Symbols as Market Maker in lieu of the Tier 5 rebate.”

Second, for the NOM Market Maker rebate to add liquidity in penny symbols, NOM proposes to increase the applicable monthly percentage volume for Participants to achieve Tier 5 status from 1.00% to 1.25%. Currently, to achieve Tier 5 status, a Participant must (a) add NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 1.00% of total industry customer equity and ETF option ADV contracts per day in a month; or (b) add NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols above 0.40% of total industry customer equity and ETF option ADV contracts per day in a month and transacts in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.40% or more of Consolidated Volume (“CV”) which adds liquidity in the same month on The Nasdaq Stock Market. NOM proposes to change “1.00% of total industry customer equity and ETF option ADV contracts per day in a month” to 1.25% of total industry customer equity and ETF option ADV contracts per day in a month.

Last, NOM proposes to amend the note 6 incentive to allow Participants that qualify for either the Tier 5 or 6 NOM Market Maker Rebate to Add Liquidity in Penny Symbols to receive a \$0.86 per contract NOM Market Maker Rebate to Add Liquidity in Non-Penny Symbols. The Exchange believes that these above changes will attract a greater amount of order flow to NOM to

the benefit of other Participants who may interact with that order flow.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁸ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,⁹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”¹⁰

Likewise, in *NetCoalition v. Securities and Exchange Commission*¹¹ (“NetCoalition”) the D.C. Circuit upheld the Commission’s use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.¹² As the court emphasized, the Commission “intended in Regulation NMS that ‘market forces, rather than regulatory requirements’ play a role in determining the market data . . . to be made available to investors and at what cost.”¹³

Further, “[n]o one disputes that competition for order flow is ‘fierce.’ . . . As the SEC explained, ‘[i]n the U.S.

national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution’; [and] ‘no exchange can afford to take its market share percentages for granted’ because ‘no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers’. . . .”¹⁴ Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

The Exchange’s proposal to increase the Tier 5 rebate for adding liquidity in penny symbols by NOM Market Makers and remove the corresponding note 11 incentive is reasonable because it will attract additional order flow to NOM and all NOM Market Makers would be eligible to receive the \$0.46 per contract rebate to add liquidity in Penny Symbols. Further, the proposal aligns with the goals of the note 6 incentive, which would allow Participants that qualify for either the Tier 5 or 6 NOM Market Maker Rebate to Add Liquidity in Penny Symbols to receive a \$0.86 per contract NOM Market Maker Rebate to Add Liquidity in Non-Penny Symbols. The Exchange’s proposal to increase the applicable monthly percentage volume for Participants to achieve Tier 5 status for the NOM Market Maker rebate to add liquidity in penny symbols is reasonable because of the corresponding *increase* to the rebate for adding liquidity in penny symbols by NOM Market Makers. Additionally, the Exchange’s proposal to amend the note 6 incentive for Participants is reasonable because it would allow Participants that qualify for the Tier 5 NOM Market Maker Rebate to receive a \$0.86 per contract NOM Market Maker Rebate to Add Liquidity in Non-Penny Symbols which may attract additional order flow to the Exchange. To the extent NOM Market Maker Participants continue to add liquidity in penny symbols on NOM to meet the proposed volume threshold to

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(4) and (5).

¹⁰ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (“Regulation NMS Adopting Release”).

¹¹ *NetCoalition v. SEC*, 615 F.3d 525 (D.C. Cir. 2010).

¹² See *NetCoalition*, at 534–535.

¹³ *Id.* at 537.

¹⁴ *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

receive the incentive, the Exchange believes that its proposal will benefit all market participants who will be able to interact with the additional liquidity.

The Exchange's proposal to increase the rebate for adding liquidity in penny symbols by all NOM Market Makers and remove the corresponding note 11 incentive is equitable and not unfairly discriminatory because the Exchange will uniformly assess all NOM Market Makers the applicable penny symbol rebate for adding liquidity provided they meet the requirements for the rebate. The Exchange's proposal to increase the applicable monthly percentage volume for Participants to achieve Tier 5 status for the NOM Market Maker rebate to add liquidity in penny symbols is equitable and not unfairly discriminatory because the Exchange will uniformly assess all NOM Market Makers with the applicable monthly percentage volume in determining whether they meet the requirements for the rebate. The Exchange's proposal to amend the note 6 incentive for Participants is equitable and not unfairly discriminatory because the Exchange will uniformly assess all NOM Market Makers the applicable penny symbol rebate for adding liquidity provided they meet the requirements for the rebate.

The Exchange's proposed differentiation between NOM Market Makers and other market participants is equitable and not unfairly discriminatory because it recognizes the differing contributions of NOM Market Makers. NOM Market Makers have obligations to the market and regulatory requirements which do not apply to other market participants.¹⁵ A NOM Market Maker has the obligation, for example, to make continuous markets, engage in a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and not make bids or offers or enter into transactions that are inconsistent with a course of dealings.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Inter-Market Competition

The proposal does not impose an undue burden on inter-market competition. The Exchange believes its proposal remains competitive with other options markets. The Exchange

notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges. Because competitors are free to modify their own fees and rebates in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee and rebate changes in this market may impose any burden on competition is extremely limited.

Intra-Market Competition

The Exchange's proposal to (1) increase the rebate for adding liquidity in penny symbols by NOM Market Makers and remove the corresponding note 11 incentive (2) increase the applicable monthly percentage volume for Participants to achieve Tier 5 status, and (3) amend the note 6 incentive for Participants does not impose an undue burden on competition. Offering these discounts to NOM Market Makers does not impose an undue burden on competition because NOM Market Makers have obligations to the market and regulatory requirements which do not apply to other market participants.¹⁶ A NOM Market Maker has the obligation, for example, to make continuous markets, engage in a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and not make bids or offers or enter into transactions that are inconsistent with a course of dealings. The proposed differentiation as between NOM Market Makers and other market participants recognizes the differing contributions of NOM Market Makers. For the above reasons, the Exchange believes that NOM Market Makers are entitled to discounted fees, provided they qualify for the discount.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.¹⁷

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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-NASDAQ-2025-045 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NASDAQ-2025-045. 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,

¹⁵ See NOM Options 2, Sections 4 and 5.

¹⁶ See NOM Options 2, Sections 4 and 5.

¹⁷ 15 U.S.C. 78s(b)(3)(A)(ii).

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–NASDAQ–2025–045 and should be submitted on or before July 23, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025–12299 Filed 7–1–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103344; File No. SR–ISE–2024–62]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendments No. 2 and 3, Regarding Position and Exercise Limits for Options on the iShares Bitcoin Trust ETF

June 27, 2025.

On December 20, 2024, pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder,² Nasdaq ISE, LLC (“Exchange”) filed with the Securities and Exchange Commission (“Commission”) a proposed rule change to apply the position and exercise limits in Options 9, Sections 13 and 15 to options on the iShares Bitcoin Trust ETF (“IBIT”) and to provide for the trading of flexible exchange options on IBIT. The proposed rule change was published for comment in the **Federal Register** on January 6, 2025.³ On February 20, 2025, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which

to approve the proposal, disapprove the proposal, or institute proceedings to determine whether to disapprove the proposal.⁵ On March 6, 2025, the Exchange submitted Amendment No. 1 to the proposal, which superseded the original filing in its entirety. On March 14, 2025, the Commission published Amendment No. 1 for notice and comment and instituted proceedings pursuant to Section 19(b)(2)(B) of the Act⁶ to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.⁷ On March 26, 2025, the Exchange withdrew Amendment No. 1 and filed Amendment No. 2, which superseded Amendment No. 1 in its entirety.⁸ On May 27, 2025, the Exchange filed Amendment No. 3 to the proposal.⁹

Section 19(b)(2) of the Act¹⁰ provides that, after initiating disapproval proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on January 6, 2025.¹¹ July 5, 2025, is 180 days from that date, and September 3, 2025, is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change, as modified by Amendments No. 2 and 3, so that it has sufficient time to consider the proposed rule change, as modified by Amendments No. 2 and 3, and the comments received. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,¹² designates September 3, 2025, as the date by which the Commission shall either approve or disapprove the proposed rule change (File No. SR–ISE–

2024–62), as modified by Amendments No. 2 and 3.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025–12303 Filed 7–1–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103341; File No. SR–NASDAQ–2025–047]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Equity 4, Rule 4754(b)(4) To Modify How the Nasdaq Official Closing Price Will Be Determined for a Nasdaq-Listed ETP

June 27, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder,² notice is hereby given that on June 24, 2025, The Nasdaq Stock Market LLC (“Nasdaq” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Equity 4, Rule 4754(b)(4) to modify how the Nasdaq Official Closing Price (“NOCP”) will be determined for a Nasdaq-listed exchange-traded product (“ETP”) with a closing cross (“Closing Cross”) trade of less than one round lot.

The text of the proposed rule change is available on the Exchange’s website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements

¹³ 17 CFR 200.30–3(a)(57).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

⁵ See Securities Exchange Act Release No. 102463, 90 FR 10736 (Feb. 26, 2025).

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Securities Exchange Act Release No. 102682, 90 FR 13233 (Mar. 20, 2025).

⁸ Amendment No. 2 is available at: <https://www.sec.gov/comments/sr-ise-2024-62/srise202462-593575-1721782.pdf>.

⁹ Amendment No. 3 is available at: <https://www.sec.gov/comments/sr-ise-2024-62/srise202462-606647-1771694.pdf>.

¹⁰ 15 U.S.C. 78s(b)(2).

¹¹ See *supra* note 3.

¹² *Id.*

¹⁸ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 102065 (Dec. 31, 2024), 90 FR 704. Comments on the proposal are available at: <https://www.sec.gov/comments/sr-ise-2024-62/srise202462.htm>.

⁴ 15 U.S.C. 78s(b)(2).

concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Equity 4, Rule 4754(b)(4) to modify how the NOCP³ will be determined for a Nasdaq-listed ETP with a Closing Cross trade of less than one round lot (*i.e.*, an odd lot). The proposal is substantively identical to the process described in Cboe BZX Exchange, Inc. ("BZX") Rule 11.23(c)(2)(B) for BZX-listed ETPs⁴ and NYSE Arca, Inc. ("Arca") Rule 1.1 for Arca-listed ETPs.⁵

Nasdaq Rule 4754(b) specifies the processing of the Closing Cross, including how the Exchange determines the NOCP for a Nasdaq-listed ETP if the Exchange does not conduct a Closing Cross. Today, as set forth in Rule 4754(b)(4), for stocks that participate in the Closing Cross (including ETPs), the Closing Cross price is the NOCP. Rule 4754(b)(4)(A) provides that if the ETP does not have a Closing Cross, then the time-weighted average midpoint ("T-WAM") of the national best bid and offer ("NBBO") is used as the NOCP. Rule 4754(b)(4)(A)(i) and (ii) go into detail of how T-WAM is calculated based on the spreads from the last two minutes of the day for ETPs.⁶ The Exchange adopted the T-WAM method for deriving the NOCP for ETPs so that the NOCP would be more indicative of the actual value of the ETPs, in particular for ETPs that are thinly traded.⁷

³ As set forth in Rule 4754(b)(4), the NOCP is the Closing Cross price for stocks that participate in the Closing Cross.

⁴ See also Securities Exchange Act Release Nos. 84738 (Dec. 6, 2018), 83 FR 63932 (Dec. 12, 2018) (SR-CboeBZX-2018-079); and 93616 (November 19, 2021), 86 FR 67524 (November 26, 2021) (SR-CboeBZX-2021-073) (collectively, "BZX Filings").

⁵ See Arca Rule 1.1, "Official Closing Price." See also Securities Exchange Act Release Nos. 82907 (March 20, 2018), 83 FR 12980 (March 26, 2018) (SR-NYSEArca-2018-08); and 84471 (October 23, 2018) 83 FR 54384 (October 29, 2018) (SR-NYSEArca-2018-63) (collectively, "Arca Filings").

⁶ See also <https://www.nasdaq.com/docs/enhanced-closing-price-for-ETPs>.

⁷ See Securities Exchange Act Release No. 87486 (November 7, 2019), 84 FR 61952 (November 14, 2019) (SR-NASDAQ-2019-061) ("T-WAM Rule Change").

The Exchange now proposes to expand the use of T-WAM to one other scenario, specifically when there is less than one round lot executed in the Closing Cross. Accordingly, Rule 4754(b)(A) will be amended to provide that if a Nasdaq-listed ETP does not have a Closing Cross, or if a closing cross trade is less than one round lot, then the T-WAM of the NBBO will be used as the NOCP. The proposed rule change is intended to make the NOCP more reflective of the value of the Nasdaq-listed ETP, particularly ones that are less actively traded and do not have consistent order interest on a daily basis to have a round lot trade in the Closing Cross. Today, if an odd lot is executed in the Closing Cross for a Nasdaq-listed ETP, the Exchange determines the Closing Cross price pursuant to the methodology set out in Rule 4754(b)(2) and that Closing Cross price would be published as the NOCP for the ETP. Instead of the current methodology, the Exchange believes that using the T-WAM of the NBBO would be more indicative of the actual value of the ETP, which in turn will provide investors and issuers with a more accurate price to mark performance of their funds and portfolios. As noted above, both Arca and BZX currently have substantively identical processes.⁸

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁹ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁰ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange believes that the proposed rule change is consistent with the Act because it would apply the T-WAM method described above to determine the NOCP in a Nasdaq-listed ETP if its Closing Cross trade is less than one round lot, which will result in a NOCP that is more indicative of the actual value of the ETP. By using the T-WAM of the NBBO (*i.e.*, a more accurate representation of the value of the ETP), the Exchange believes this will provide investors and issuers with a more

⁸ See *supra* notes 4 and 5. As stated in the BZX Filings and Arca Filings, the exchanges use the time-weighted average price of the midpoint of the NBBO to determine the official closing price if there is no closing auction or if a closing auction trade is less than a round lot.

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

accurate price to mark performance of their funds and portfolios. As noted above, the proposed rule change is substantively identical to the processes at Arca and BZX.¹¹

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is substantively identical to the processes currently in place at other exchanges, and is designed to provide for how the Exchange would determine the NOCP for a Nasdaq-listed ETP if there was less than one round lot trade in the Closing Cross. The Exchange believes that its proposal to align with other exchanges will help it better compete as a listing venue.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A) of the Act¹² and Rule 19b-4(f)(6)¹³ thereunder, the Exchange has designated this proposal as one that effects a change that: (i) does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.¹⁴

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)¹⁵ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day

¹¹ See *supra* note 8.

¹² 15 U.S.C. 78s(b)(3)(A).

¹³ 17 CFR 240.19b-4(f)(6).

¹⁴ 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.

¹⁵ 17 CFR 240.19b-4(f)(6)(iii).

operative delay so that it may implement the proposed rule change by July 12, 2025. As the Exchange explains above, its proposal to utilize a time-weighted average to derive the closing price for an ETP under certain circumstances is not novel. Furthermore, the Exchange argues that a T-WAM NOCP would be more indicative of the actual value of an ETP when that ETP closes with an odd-lot execution. As such, the Commission believes that it is consistent with the protection of investors and the public interest for the Exchange to implement this proposal prior to 30-days from the date of filing. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.¹⁶

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NASDAQ-2025-047 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to file number SR-NASDAQ-2025-047. 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-NASDAQ-2025-047 and should be submitted on or before July 23, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-12301 Filed 7-1-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-103340; File No. SR-CBOE-2025-017]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of Amendment No. 4 and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 4, To Amend Rules 4.3, 4.20, and 8.30, To Allow the Exchange To List and Trade Options on the VanEck Bitcoin ETF

June 27, 2025.

On March 14, 2025, Cboe Exchange, Inc. ("Cboe" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to list and trade options on the

VanEck Bitcoin Trust.³ On March 26, 2025, the Exchange filed Amendment No. 1 to the proposed rule change. On March 27, 2025, the Exchange withdrew Amendment No. 1, filed and withdrew Amendment No. 2, and filed Amendment No. 3 to the proposal, which superseded and replaced the original proposal in its entirety.⁴ The proposed rule change, as modified by Amendment No. 3, was published for comment in the **Federal Register** on April 3, 2025.⁵ On May 1, 2025, the Exchange filed Amendment No. 4 to the proposed rule change, described in Items I and II below, which Items have been prepared by the Exchange. Amendment No. 4 supersedes the initial proposed rule change and Amendment Nos. 1 through 3 and replaces them in their entirety.⁶ On May 14, 2025, 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, as modified by Amendment No. 4.⁷

The Commission is publishing this notice to solicit comments on Amendment No. 4 from interested persons and is instituting proceedings under Section 19(b)(2)(B) of the Act⁸ to determine whether to approve or

³ On January 10, 2024, the Commission approved proposals by NYSE Arca, Inc., The Nasdaq Stock Market LLC, and Cboe BZX Exchange, Inc. to list and trade the shares of 11 spot bitcoin-based commodity-based trust shares and trust units, including the trust underlying the proposed options herein. See Securities Exchange Act Release No. 99306 (Jan. 10, 2024), 89 FR 3008 (Jan. 17, 2024) (order approving File Nos. SR-NYSEARCA-2021-90; SR-NYSEARCA-2023-44; SR-NYSEARCA-2023-58; SR-NASDAQ-2023-016; SR-NASDAQ-2023-019; SR-CboeBZX-2023-028; SR-CboeBZX-2023-038; SR-CboeBZX-2023-040; SR-CboeBZX-2023-042; SR-CboeBZX-2023-044; SR-CboeBZX-2023-072) ("Bitcoin ETP Order").

⁴ Amendment No. 3 modified the original filing by (1) adding information regarding the proposed changes to Rule 4.20; and (2) correcting minor technical errors.

⁵ See Securities Exchange Act Release No. 102742 (Mar. 28, 2025), 90 FR 14670. The Commission did not receive any comments regarding the proposal.

⁶ Amendment No. 4 modifies the original filing, as modified by Amendment No. 3, by (1) changing references to the VanEck Bitcoin Trust to the VanEck Bitcoin ETF and (2) correcting a description of the 30-day period over which average daily volume was measured for shares of the VanEck Bitcoin ETF. Amendment No. 4 is available at <https://www.sec.gov/comments/sr-cboe-2025-017/sr-cboe2025017-600895-1751482.pdf>.

⁷ See Securities Exchange Act Release No. 103046, 90 FR 21524 (May 20, 2025). The Commission designated July 2, 2025, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change as modified by Amendment No. 4.

⁸ 15 U.S.C. 78s(b)(2)(B).

¹⁶ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁷ 17 CFR 200.30-3(a)(12), (59).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

disapprove the proposed rule change, as modified by Amendment No. 4.

I. The Exchange's Description of the Proposed Rule Change, as Modified by Amendment No. 4

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to amend Rules 4.3, 4.20, and 8.30, to allow the Exchange to list and trade options on the VanEck Bitcoin ETF. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 4.3 regarding the criteria for underlying securities. Specifically, the Exchange proposes to amend Rule 4.3, Interpretation and Policy .06(a)(4) to allow the Exchange to list and trade options on Units⁹ that represent interests in the VanEck Bitcoin ETF,¹⁰ designating them as "Units" deemed appropriate for options trading on the Exchange. Current Rule 4.3, Interpretation and Policy .06 provides that, subject to certain other criteria set forth in that Rule, securities deemed

appropriate for options trading include Units that represent certain types of interests,¹¹ including interests in certain specific trusts that hold financial instruments, money market instruments, or precious metals (which are deemed commodities).

The VanEck Bitcoin ETF is a Bitcoin-backed commodity ETF structured as a trust. Similar to any Unit currently deemed appropriate for options trading under Rule 4.3, Interpretation and Policy .06, the investment objective of the VanEck Bitcoin ETF is for its shares to reflect the performance of Bitcoin

¹¹ See Rule 4.3, Interpretation and Policy .06(a), which permits options trading on Units that represent (1) interests in registered investment companies (or series thereof) organized as open-end management investment companies, unit investment trusts or similar entities that hold portfolios of securities and/or financial instruments including, but not limited to, stock index futures contracts, options on futures, options on securities and indexes, equity caps, collars and floors, swap agreements, forward contracts, repurchase agreements and reverse purchase agreements (the "Financial Instruments"), and money market instruments, including, but not limited to, U.S. government securities and repurchase agreements (the "Money Market Instruments") comprising or otherwise based on or representing investments in indexes or portfolios of securities and/or Financial Instruments and Money Market Instruments (or that hold securities in one or more other registered investment companies that themselves hold such portfolios of securities and/or Financial Instruments and Money Market Instruments); (2) interests in a trust or similar entity that holds a specified non-U.S. currency deposited with the trust or similar entity when aggregated in some specified minimum number may be surrendered to the trust by the beneficial owner to receive the specified non-U.S. currency and pays the beneficial owner interest and other distributions on deposited non-U.S. currency, if any, declared and paid by the trust ("Currency Trust Shares"); (3) commodity pool interests principally engaged, directly or indirectly, in holding and/or managing portfolios or baskets of securities, commodity futures contracts, options on commodity futures contracts, swaps, forward contracts and/or options on physical commodities and/or non-U.S. currency ("Commodity Pool Units"); (4) represent interests in the SPDR Gold Trust, the iShares COMEX Gold Trust, the iShares Silver Trust, the Aberdeen Standard Physical Silver Trust, the Aberdeen Standard Physical Gold Trust, the Aberdeen Standard Physical Palladium Trust, the Aberdeen Standard Physical Platinum Trust, the Sprott Physical Gold Trust, the Goldman Sachs Physical Gold ETF, the Fidelity Wise Origin Bitcoin Fund, the ARK 21Shares Bitcoin ETF, the iShares Bitcoin Trust, the Grayscale Bitcoin Trust, the Grayscale Bitcoin Mini Trust, or the Bitwise Bitcoin ETF; or (5) an interest in a registered investment company ("Investment Company") organized as an open-end management investment company or similar entity, that invests in a portfolio of securities selected by the Investment Company's investment adviser consistent with the Investment Company's investment objectives and policies, which is issued in a specified aggregate minimum number in return for a deposit of a specified portfolio of securities and/or a cash amount with a value equal to the next determined net asset value ("NAV"), and when aggregated in the same specified minimum number, may be redeemed at a holder's request, which holder will be paid a specified portfolio of securities and/or cash with a value equal to the next determined NAV ("Managed Fund Share").

(less the expenses of the trust's operations), offering investors an opportunity to gain exposure to Bitcoin without the complexities of Bitcoin delivery. As is the case for Units currently deemed appropriate for options trading, the VanEck Bitcoin ETF's shares represent units of fractional undivided beneficial interest in the trust, the assets of which consist principally of Bitcoin and are designed to track Bitcoin or the performance of the price of Bitcoin and offer access to the Bitcoin market.¹² The VanEck Bitcoin ETF provides investors with cost-efficient alternatives that allow a level of participation in the Bitcoin market through the securities market.

The Exchange believes the VanEck Bitcoin ETF satisfies the Exchange's initial listing standards for Units on which the Exchange may list options. Specifically, the VanEck Bitcoin ETF satisfies the initial listing standards set forth in Rule 4.3, Interpretation and Policy .06(b), as is the case for other Units on which the Exchange lists options (including trusts that hold commodities). Rule 4.3, Interpretation and Policy .06 requires that Units must either (1) meet the criteria and standards set forth in Rule 4.3, Interpretation and Policy .01(a),¹³ or (2) be available for creation or redemption each business day from or through the issuer in cash or in kind at a price related to net asset value, and the issuer must be obligated to issue Units in a specified aggregate number even if some or all of the investment assets required to be deposited have not been received by the issuer, subject to the condition that the person obligated to deposit the investments has undertaken to deliver the investment assets as soon as possible and such undertaking is secured by the delivery and maintenance of collateral consisting of cash or cash equivalents satisfactory to the issuer, as provided in the respective prospectus. The VanEck Bitcoin ETF satisfies Rule 4.3, Interpretation and Policy .06(b)(2), as each is subject to this creation and redemption process.

While not required by the Rules for purposes of options listings, the Exchange believes the VanEck Bitcoin ETF satisfies the criteria and guidelines set forth in Rule 4.3, Interpretation and Policy .01. Pursuant to Rule 4.3(a), a security (which includes a Unit) on which options may be listed and traded

¹² The trust may include minimal cash and cash equivalents (*i.e.*, short-term instruments with maturities of less than three months).

¹³ Rule 4.3, Interpretation and Policy .01 provides for guidelines to be by the Exchange when evaluating potential underlying securities for Exchange option transactions.

⁹ Rule 1.1 defines a "Unit" (which may also be referred to as an ETF) as a share or other security traded on a national securities exchange and defined as an NMS stock as set forth in Rule 4.3.

¹⁰ See Securities Exchange Act Release No. 99306 (January 10, 2024), 89 FR 3008 (January 17, 2024) (SR-CboeBZX-2023-040) (Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, to List and Trade Bitcoin-Based Commodity-Based Trust Shares and Trust Units) ("Bitcoin ETP Approval Order").

on the Exchange must be duly registered (with the Commission) and be an NMS stock (as defined in Rule 600 of Regulation NMS under the Securities Exchange Act of 1934, as amended (the “Act”)), and be characterized by a substantial number of outstanding shares that are widely held and actively traded.¹⁴ The VanEck Bitcoin ETF is an NMS Stock as defined in Rule 600 of Regulation NMS under the Act.¹⁵ The Exchange believes the VanEck Bitcoin ETF is characterized by a substantial number of outstanding shares that are widely held and actively traded.

As of March 5, 2025, the VanEck Bitcoin ETF had the following number of shares outstanding:

Bitcoin fund	Shares outstanding
VanEck Bitcoin ETF	49,900,000

The VanEck Bitcoin ETF had significantly more than 7,000,000 shares outstanding (approximately 7 times that amount), which is the minimum number of shares of a corporate stock that the Exchange generally requires to list options on that stock pursuant to Rule 4.3, Interpretation and Policy .01(a)(1). The Exchange believes this demonstrates that the VanEck Bitcoin ETF is characterized by a substantial number of outstanding shares.

Further, the below table contains information regarding the number of beneficial holders of the VanEck Bitcoin ETF as of the specified dates:

Bitcoin fund	Beneficial holders	Date
VanEck Bitcoin ETF	32,469	1/31/25

As this table shows, the VanEck Bitcoin ETF has significantly more than 2,000 beneficial holders (approximately 16 times more), which is the minimum number of holders the Exchange generally requires for corporate stock in order to list options on that stock pursuant to Rule 4.3, Interpretation and Policy .01(a)(2). Therefore, the Exchange believes the shares of the VanEck Bitcoin ETF are widely held.¹⁶

The Exchange also believes the shares of the VanEck Bitcoin ETF are actively traded. As of March 5, 2025, the total trading volume (by shares) for the trust for the six-month period of September 5, 2024, through March 5, 2025, and the approximate average daily volume (“ADV”) (in shares and notional) over the 30-day period of January 21, 2025, through March 5, 2025, for the VanEck Bitcoin ETF was as follows:

Bitcoin fund	6-Month trading volume (shares)	30-Day ADV (shares)	30-Day ADV (notional \$)
VanEck Bitcoin ETF	133,275,448	794,677	39,163,513.72

As demonstrated above, as of March 5, 2025, the six-month trading volume for the VanEck Bitcoin ETF as of that date was substantially higher than 2,400,000 shares (approximately 55 times that amount), which is the minimum 12-month volume the Exchange generally requires for a corporate stock in order to list options on that security as set forth in Rule 4.3, Interpretation and Policy .01. The Exchange believes this data demonstrates the VanEck Bitcoin ETF is characterized as having shares that are actively traded.

Options on the VanEck Bitcoin ETF will be subject to the Exchange’s continued listing standards set forth in Rule 4.4, Interpretation and Policy .06 for Units deemed appropriate for options trading pursuant to Rule 4.3, Interpretation and Policy .06. Specifically, Rule 4.4, Interpretation and Policy .06 provides that Units that were initially approved for options trading pursuant to Rule 4.3, Interpretation and Policy .06 shall be deemed not to meet

the requirements for continued approval, and the Exchange shall not open for trading any additional series of option contracts of the class covering that such Units, if the Units cease to be an NMS stock or the Units are halted from trading in their primary market. Additionally, options on Units may be subject to the suspension of opening transactions in any of the following circumstances: (1) in the case of options covering Units approved for trading under Rule 4.3, Interpretation and Policy .06(b)(1), in accordance with the terms of paragraphs (a), (b), and (c) of Rule 4.4, Interpretation and Policy .01; (2) in the case of options covering Units approved for trading under Rule 4.3 Interpretation and Policy .06(b)(2) (as is the case for the VanEck Bitcoin ETF), following the initial twelve-month period beginning upon the commencement of trading in the Units on a national securities exchange and are defined as an NMS stock, there are fewer than 50 record and/or beneficial holders of such Units for 30 or more

consecutive trading days; (3) the value of the index or portfolio of securities, non-U.S. currency, or portfolio of commodities including commodity futures contracts, options on commodity futures contracts, swaps, forward contracts and/or options on physical commodities and/or financial instruments and money market instruments on which the Units are based is no longer calculated or available; or (4) such other event shall occur or condition exist that in the opinion of the Exchange makes further dealing in such options on the Exchange inadvisable.

Options on the VanEck Bitcoin ETF will be physically settled contracts with American-style exercise.¹⁷ Consistent with current Rule 4.5, which governs the opening of options series on a specific underlying security (including Units), the Exchange will open at least one expiration month for options on the

¹⁴ The criteria and guidelines for a security to be considered widely held and actively traded are set forth in Rule 4.3, Interpretation and Policy .01, subject to exceptions.

¹⁵ An “NMS stock” means any NMS security other than an option, and an “NMS security” means any security or class of securities for which transaction reports are collected, processed, and made available pursuant to an effective transaction reporting plan (or an effective national market system plan for reporting transaction in listed

options). See 17 CFR 242.600(b)(64) (definition of “NMS security”) and (65) (definition of “NMS stock”).

¹⁶ The Exchange continues to believe assets under management (“AUM”), rather than shares outstanding and number of holders, is a better measure of investable capacity of ETFs and a more appropriate figure for determining position and exercise limits of ETFs and looks forward to further discussions with the Commission staff on this topic.

¹⁷ See Rule 4.2, which provides that the rights and obligations of holders and writers are set forth in the Rules of the Options Clearing Corporation (“OCC”); and Equity Options Product Specifications January 3, 2024), available at Equity Options Specifications (cboe.com); see also OCC Rules, Chapters VIII (which governs exercise and assignment) and Chapter IX (which governs the discharge of delivery and payment obligations arising out of the exercise of physically settled stock option contracts).

VanEck Bitcoin ETF¹⁸ at the commencement of trading on the Exchange and may also list series of options on the VanEck Bitcoin ETF for trading on a weekly,¹⁹ monthly,²⁰ or quarterly²¹ basis. The Exchange may also list long-term equity option series (“LEAPS”) that expire from 12 to 180 months from the time they are listed.

Pursuant to Rule 4.5, Interpretation and Policy .07, which governs strike prices of series of options on Units, the interval of strikes prices for series of options on the VanEck Bitcoin ETF will be \$1 or greater when the strike price is \$200 or less and \$5 or greater where the strike price is over \$200.²² Additionally, the Exchange may list series of options pursuant to the \$1 Strike Price Interval Program,²³ the \$0.50 Strike Program,²⁴ the \$2.50 Strike Price Program,²⁵ and the \$5 Strike Program.²⁶ Pursuant to Rule 5.4, where the price of a series of the VanEck Bitcoin ETF option is less than \$3.00, the minimum increment will be \$0.05, and where the price is \$3.00 or higher, the minimum increment will be \$0.10.²⁷ Any and all new series of VanEck Bitcoin ETF options that the Exchange lists will be

consistent and comply with the expirations, strike prices, and minimum increments set forth in Rules 4.5 and 5.4, as applicable.

VanEck Bitcoin ETF options will trade in the same manner as any other Unit options on the Exchange. The Exchange Rules that currently apply to the listing and trading of all Unit options on the Exchange, including, for example, Rules that govern listing criteria, expirations, exercise prices, minimum increments, margin requirements, customer accounts, and trading halt procedures will apply to the listing and trading of VanEck Bitcoin ETF options on the Exchange in the same manner as they apply to other options on all other Units that are listed and traded on the Exchange, including the precious-metal backed commodity Units already deemed appropriate for options trading on the Exchange pursuant to current Rule 4.3, Interpretation and Policy .06(a)(4).

Rule 4.20 currently permits the Exchange to authorize for trading a FLEX option class on any equity security if it may authorize for trading a non-FLEX option class on that equity

security pursuant to Rule 4.3. The proposed rule change amends Rule 4.20 to exclude the VanEck Bitcoin ETF from this provision.

The Exchange also proposes to amend Rule 8.30. Specifically, the Exchange proposes to amend Rule 8.30, Interpretation and Policy .10 to provide a position limit of 25,000 same side option contracts for the VanEck Bitcoin ETF option. Additionally, pursuant to Rule 8.42, Interpretation and Policy .02, the exercise limits for options on the VanEck Bitcoin ETF will be equivalent to this proposed position limit.

The Exchange determined these proposed position and exercise limits considering, among other things, the approximate six-month average daily volume (“ADV”) and outstanding shares of the VanEck Bitcoin ETF (which as discussed above demonstrate that the VanEck Bitcoin ETF is widely held and actively traded and thus justify these conservatively proposed position limits), as set forth below, along with market capitalization (as of March 5, 2025):

Underlying Bitcoin fund	Six-Month ADV (shares)	Outstanding shares	Market capitalization (\$)
VanEck Bitcoin ETF	1,074,802	49,900,000	1,271,859,416

The Exchange then compared the number of outstanding shares of the VanEck Bitcoin ETF to those of other ETFs. The following table provides the approximate average position (and exercise limit) of ETF options with similar outstanding shares (as of March 5, 2025), compared to the proposed position and exercise limit for the VanEck Bitcoin ETF options:

Underlying Bitcoin fund	Average limit of other ETF options (contracts)	Proposed limit (con- tracts)
VanEck Bitcoin ETF	225,000 *	25,000

* Over 90% of the ETFs used for comparison have a limit of at least 200,000, and more than 75% have a limit of 250,000.

The Exchange considered current position and exercise limits of options on ETFs with outstanding shares comparable to those of the VanEck Bitcoin ETF, with the proposed limit significantly lower (between two and

ten times lower) than the average limits of the options on the other ETFs. As discussed above, the VanEck Bitcoin ETF is actively held and widely traded (all statistics as of March 5, 2025) because it: (1) had significantly more than 7,000,000 shares outstanding, which is the minimum number of shares of a corporate stock that the Exchange generally requires to list options on that stock pursuant to Rule 4.3, Interpretation and Policy .01(a)(1); (2) had significantly more than 2,000 beneficial holders, which is the minimum number of holders the Exchange generally requires for

¹⁸ See Rule 4.5(b). The monthly expirations are subject to certain listing criteria for underlying securities described within Rule 4.3. Monthly listings expire the third Friday of the month. The term “expiration date” (unless separately defined elsewhere in the OCC By-Laws), when used in respect of an option contract (subject to certain exceptions), means the third Friday of the expiration month of such option contract, or if such Friday is a day on which the exchange on which such option is listed is not open for business, the preceding day on which such exchange is open for business. See OCC By-Laws Article I, Section 1. Pursuant to Rule 4.5(c), additional series of options of the same class may be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer

demand or when the market price of the underlying stock moves more than five strike prices from the initial exercise price or prices. New series of options on an individual stock may be added until the beginning of the month in which the options contract will expire. Due to unusual market conditions, the Exchange, in its discretion, may add a new series of options on an individual stock until the close of trading on the business day prior to expiration.

¹⁹ See Rule 4.5(d).

²⁰ See Rule 4.5(g).

²¹ See Rule 4.5(e).

²² The Exchange notes that for options listed pursuant to the Short Term Option Series Program, the Monthly Options Series Program, and the

Quarterly Options Series Program, Rules 4.5(d), (e), and (g) specifically sets forth intervals between strike prices on Quarterly Options Series, Short Term Option Series, and Monthly Options Series, respectively.

²³ See Rule 4.5, Interpretation and Policy .01(a).

²⁴ See Rule 4.5, Interpretation and Policy .01(b).

²⁵ See Rule 4.5, Interpretation and Policy .04.

²⁶ See Rule 4.5, Interpretation and Policy .01(f).

²⁷ If options on the VanEck Bitcoin ETF are eligible to participate in the Penny Interval Program, the minimum increment will be \$0.01 for series with a price below \$3.00 and \$0.05 for series with a price at or above \$3.00. See 5.4(d) (which describes the requirements for the Penny Interval Program).

corporate stock in order to list options on that stock pursuant to Rule 4.3, Interpretation and Policy .01(a)(2); and (3) had a six-month trading volume substantially higher than 2,400,000 shares, which is the minimum 12-month

volume the Exchange generally requires for a security in order to list options on that security as set forth in Rule 4.3, Interpretation and Policy .01.

With respect to outstanding shares, if a market participant held the maximum number of positions possible pursuant

to the proposed position and exercise limits, the equivalent shares represented by the proposed position/exercise limit would represent the following approximate percentage of current outstanding shares:

Underlying Bitcoin fund	Proposed position/ exercise limit (in equivalent shares)	Outstanding shares	Percentage of outstanding shares (%)
VanEck Bitcoin ETF	2,500,000	49,900,000	5.01

As this table demonstrates, if a market participant held the maximum permissible options positions in VanEck Bitcoin ETF options and exercised all of them at the same time, that market participant would control a small percentage of the outstanding shares of the VanEck Bitcoin ETF.

Cboe Options Rule 8.30, Interpretation and Policy .02, provides two methods of qualifying for a position limit tier above 25,000 option contracts. The first method is based on six-month

trading volume in the underlying security, and the second method is based on slightly lower six-month trading volume *and* number of shares outstanding in the underlying security. An underlying stock or ETF that qualifies for method two based on trading volume and number of shares outstanding would be required to have the minimum number of outstanding shares as shown in middle column of the table below.

The table, which provides the equivalent shares of the position limits applicable to equity options, including ETFs, further represents the percentages of the minimum number of outstanding shares that an underlying stock or ETF must have to qualify for that position limit (under the second method described above), all of which are higher than the percentages for the VanEck Bitcoin ETF.

Position/exercise limit (in equivalent shares)	Minimum outstanding shares	Percentage of outstanding shares (%)
2,500,000	** 6,300,000	40.0
5,000,000	40,000,000	12.5
7,500,000	120,000,000	6.3
20,000,000	240,000,000	8.3
25,000,000	300,000,000	8.3

^{**} This is the minimum number of outstanding shares an underlying security must have for the Exchange to continue to list options on that security, so this would be the smallest number of outstanding shares permissible for any corporate option that would have a position limit of 25,000 contract. See Rule 4.4, Interpretation and Policy .01. This rule applies to corporate stock options but not ETF options, which currently have no requirement regarding outstanding shares of the underlying ETF for the Exchange to continue listing options on that ETF. Therefore, there may be ETF options trading for which the 25,000 contract position limits represents an even larger percentage of outstanding shares of the underlying ETF than set forth above.

The equivalent shares represented by the proposed position and exercise limits for the VanEck Bitcoin ETF as a percentage of outstanding shares of the VanEck Bitcoin ETF is significantly lower than the percentage for the lowest possible position limit for equity options of 25,000 (under 6% compared to 40%) and is lower than that percentage for each current position limit bucket.²⁸

Further, the proposed position and exercise limits for the VanEck Bitcoin ETF option are significantly below the limits that would otherwise apply pursuant to current Rule 8.30. These position and exercise limits are the

lowest position and exercise limits available in the options industry, are extremely conservative and more than appropriate given the market capitalization, average daily volume, and high number of outstanding shares of the VanEck Bitcoin ETF.

All of the above information demonstrates that the proposed position and exercise limits for the VanEck Bitcoin ETF options are more than reasonable and appropriate. The trading volume, ADV, and outstanding shares of the VanEck Bitcoin ETF demonstrate that the trust is actively traded and widely held, and proposed position and exercise limits are well below those of other ETFs with similar market characteristics. The proposed position and exercise limits are the lowest position and exercise limits available for equity options in the industry, are extremely conservative, and are more

than appropriate given the VanEck Bitcoin ETF's market capitalization, ADV, and high number of outstanding shares.

Today, the Exchange has an adequate surveillance program in place for options. Cboe intends to apply those same program procedures to options on the VanEck Bitcoin ETF that it applies to the Exchange's other options products.²⁹ Cboe's market surveillance staff would have access to the surveillances conducted by Cboe BZX Exchange, Inc.³⁰ with respect to the VanEck Bitcoin ETF and would review activity in the underlying VanEck Bitcoin ETF when conducting

²⁸ As these percentages are based on the minimum number of outstanding shares an underlying security must have to qualify for the applicable position limit, these are the highest possible percentages that would apply to any option subject to that position and exercise limit.

²⁹ The surveillance program includes surveillance patterns for price and volume movements as well as patterns for potential manipulation (e.g., spoofing and marking the close).

³⁰ Cboe BZX Exchange, Inc. is an affiliated market of the Exchange.

surveillances for market abuse or manipulation in the options on the VanEck Bitcoin ETF. Additionally, the Exchange is a member of the Intermarket Surveillance Group (“ISG”) under the ISG Agreement. ISG members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets. In addition to obtaining information from BZX, the Exchange would be able to obtain information regarding trading of shares of the VanEck Bitcoin ETF through ISG.

In addition, Cboe has a Regulatory Services Agreement with the Financial Industry Regulatory Authority (“FINRA”) for certain market surveillance, investigation and examinations functions. Pursuant to a multi-party 17d–2 joint plan, all options exchanges allocate amongst themselves and FINRA responsibilities to conduct certain options-related market surveillance that are common to rules of all options exchanges.³¹

The underlying shares of spot bitcoin exchange-traded products (“ETPs”), including the VanEck Bitcoin ETF, are also subject to safeguards related to addressing market abuse and manipulation. As the Commission stated in its order approving proposals of several exchanges to list and trade shares of spot bitcoin-based ETPs:

Each Exchange has a comprehensive surveillance-sharing agreement with the CME via their common membership in the Intermarket Surveillance Group. This facilitates the sharing of information that is available to the CME through its surveillance of its markets, including its surveillance of the CME bitcoin futures market.³²

The Exchange states that, given the consistently high correlation between the CME Bitcoin futures market and the spot bitcoin market, as confirmed by the Commission through robust correlation analysis, the Commission was able to conclude that such surveillance sharing

agreements could reasonably be “expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the [Bitcoin ETPs].”³³

In light of surveillance measures related to both options and futures as well as the VanEck Bitcoin ETF,³⁴ the Exchange believes that existing surveillance procedures are designed to deter and detect possible manipulative behavior which might potentially arise from listing and trading the proposed options on the VanEck Bitcoin ETF. Further, the Exchange will implement any new surveillance procedures it deems necessary to effectively monitor the trading of options on the VanEck Bitcoin ETF.

The Exchange has also analyzed its capacity and represents that it believes the Exchange and OPRA have the necessary systems capacity to handle the additional traffic associated with the listing of new series that may result from the introduction of options on VanEck Bitcoin ETF up to the number of expirations currently permissible under the Rules. Because the proposal is limited to two classes, the Exchange believes any additional traffic that may be generated from the introduction of VanEck Bitcoin ETF options will be manageable.

The Exchange believes that offering options on the VanEck Bitcoin ETF will benefit investors by providing them with an additional, relatively lower cost investing tool to gain exposure to the price of Bitcoin and hedging vehicle to meet their investment needs in connection with Bitcoin-related products and positions. The Exchange expects investors will transact in options on the VanEck Bitcoin ETF in the unregulated over-the-counter (“OTC”) options market,³⁵ but may prefer to trade such options in a listed environment to receive the benefits of trading listing options, including (1) enhanced efficiency in initiating and closing out positions; (2) increased market transparency; and (3) heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor of all listed options. The Exchange believes that listing the VanEck Bitcoin ETF options may cause investors to bring this liquidity to the Exchange, would increase market transparency and enhance the process of price discovery

conducted on the Exchange through increased order flow. The Units that hold financial instruments, money market instruments, or precious metal commodities on which the Exchange may already list and trade options are trusts structured in substantially the same manner as the VanEck Bitcoin ETF and essentially offer the same objectives and benefits to investors, just with respect to different assets. The Exchange notes that it has not identified any issues with the continued listing and trading of any Unit options, including Units that hold commodities (*i.e.*, precious metals) that it currently lists and trades on the Exchange.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.³⁶ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³⁷ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³⁸ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposal to list and trade options on the VanEck Bitcoin ETF will remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors because offering options on the VanEck Bitcoin ETF will provide investors with an opportunity to realize the benefits of utilizing options on the VanEck Bitcoin ETF, including cost efficiencies and increased hedging strategies. The Exchange believes that offering the VanEck Bitcoin ETF options will benefit investors by providing them with a relatively lower-cost risk management tool, which will allow them to manage

³¹ Section 19(g)(1) of the Act, among other things, requires every self-regulatory organization (“SRO”) registered as a national securities exchange or national securities association to comply with the Act, the rules and regulations thereunder, and the SRO’s own rules, and, absent reasonable justification or excuse, enforce compliance by its members and persons associated with its members. See 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d–2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO (“common members”). Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members.

³² See Bitcoin ETP Approval Order at 3009.

³³ See Bitcoin ETP Approval Order, 89 FR at 3010–11.

³⁴ See *supra* note 10.

³⁵ The Exchange understands from customers that investors have historically transacted in options on Units in the OTC options market if such options were not available for trading in a listed environment.

³⁶ 15 U.S.C. 78f(b).

³⁷ 15 U.S.C. 78f(b)(5).

³⁸ *Id.*

their positions and associated risk in their portfolios more easily in connection with exposure to the price of Bitcoin and with Bitcoin-related products and positions. Additionally, the Exchange’s offering of VanEck Bitcoin ETF options will provide investors with the ability to transact in such options in a listed market environment as opposed to in the unregulated OTC options market, which would increase market transparency and enhance the process of price discovery conducted on the Exchange through increased order flow to the benefit of all investors. The Exchange also notes that it already lists options on other commodity-based Units,³⁹ which, as described above, are trusts structured in substantially the same manner as the VanEck Bitcoin ETF and essentially offer the same objectives and benefits to investors and for which the Exchange has not identified any issues with the continued listing and trading of commodity-backed Unit options it currently lists for trading.⁴⁰

The Exchange also believes the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system, because it is consistent with current Exchange Rules previously filed with the Commission.⁴¹ Options on the VanEck Bitcoin ETF satisfy the initial listing standards and continued listing standards currently in the Exchange Rules applicable to options on all Units, including Units that hold other commodities already deemed appropriate for options trading on the Exchange. Additionally, as

demonstrated above, the VanEck Bitcoin ETF is characterized by a substantial number of shares that are widely held and actively traded. VanEck Bitcoin ETF options will trade in the same manner as any other Unit options—the same Exchange Rules that currently govern the listing and trading of all Unit options, including permissible expirations, strike prices and minimum increments, and applicable margin requirements, will govern the listing and trading of options on the VanEck Bitcoin ETF in the same manner.

The Exchange believes the proposed rule change to exclude the VanEck Bitcoin ETF from being eligible for trading as FLEX options is consistent with the Act, because it will permit the Exchange to continue to participate in ongoing discussions with the Commission regarding appropriate position limits for ETF options.⁴²

The Exchange believes the proposed position and exercise limits are designed to prevent fraudulent and manipulative acts and practices and promote just and equitable principles of trade, as they are designed to address potential manipulative schemes and adverse market impacts surrounding the use of options, such as disrupting the market in the security underlying the options. The proposed position and exercise limits in this proposal for the VanEck Bitcoin ETF options are 25,000 contracts, which is currently the lowest limit applicable to any equity options (including ETF options). The Exchange believes the proposed position and exercise limits are extremely conservative for the VanEck Bitcoin ETF option given the trading volume and

outstanding shares for each. The information above demonstrates that the average position and exercise limits of options on ETFs with comparable outstanding shares and trading volume to those of the VanEck Bitcoin ETF is significantly higher than the proposed position and exercise limits for the VanEck Bitcoin ETF options. Therefore, the proposed position and exercise limits for the VanEck Bitcoin ETF options are conservative relative to options on ETFs with comparable market characteristics.

Further, given that the issuer of the VanEck Bitcoin ETF may create and redeem shares that represent an interest in Bitcoin, the Exchange believes it is relevant to compare the size of a position limit to the market capitalization of the Bitcoin market. As of March 5, 2025, the global supply of Bitcoin was 19,832,309, and the price of one Bitcoin was approximately \$90,608.57,⁴³ which equates to a market capitalization of approximately \$1.797 trillion. Consider the proposed position and exercise limit of 25,000 option contracts for the VanEck Bitcoin ETF option. A position and exercise limit of 25,000 same side contracts effectively restricts a market participant from holding positions that could result in the receipt of no more than 2,500,000 of VanEck Bitcoin ETF shares, as applicable (if that market participant exercised all of its options). The following table shows the share price of the VanEck Bitcoin ETF on March 5, 2025, the value of 2,500,000 shares of the VanEck Bitcoin ETF at that price, and the approximate percentage of that value of the size of the Bitcoin market:

Bitcoin fund	March 5, 2025 share price (\$)	Value of 2,500,000 shares of Bitcoin fund (\$)	Percentage of Bitcoin market
VanEck Bitcoin ETF	25.60	64,000,000	0.0035

Therefore, if a market participant with the maximum 25,000 same side contracts in VanEck Bitcoin ETF options exercised all positions at one time, such an event would have no practical impact on the Bitcoin market.

The Exchange also believes the proposed limits are appropriate given position limits for Bitcoin futures. For example, the Chicago Mercantile Exchange (“CME”) imposes a position limit of 2,000 futures (for the initial spot month) on its Bitcoin futures contract.⁴⁴

On March 5, 2025, CME Mar 25 Bitcoin Futures settled at \$90,935. A position of 2,000 CME Bitcoin futures, therefore, would have a notional value of \$909,350,000. The following table shows the share price of the VanEck Bitcoin ETF on March 5, 2025, and the

³⁹ See Rule 4.3, Interpretation and Policy .06(a)(4).
⁴⁰ See Securities Exchange Act No. 101387 (October 18, 2024) 89 FR 84948 (October 24, 2024) (SR-CBOE–2024–035) (Notice of Filing of Amendment Nos. 2 and 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 2 and 3, To Permit

the Listing and Trading of Options on Bitcoin Exchange-Traded Funds).
⁴¹ *Id.*
⁴² The Exchange may submit a separate rule filing that would permit the Exchange to authorize for trading FLEX options on the VanEck Bitcoin ETF (which filing may propose changes to existing FLEX option position limits for such options if appropriate).

⁴³ See *Blockchain.com* | Charts—Total Circulating Bitcoin.
⁴⁴ See CME Rulebook Chapter 350 (description of CME Bitcoin Futures) and Chapter 5, Position Limit, Position Accountability and Reportable Level Table in the Interpretations & Special Notices. Each CME Bitcoin futures contract is valued at five Bitcoins as defined by the CME CF Bitcoin Reference Rate (“BRR”). See CME Rule 35001.

approximate number of option contracts that equates to that notional value:

Bitcoin fund	March 5, 2025 share price (\$)	Number of option contracts
VanEck Bitcoin ETF	25.60	355,214

The approximate number of option contracts for the VanEck Bitcoin ETF that equate to the notional value of CME Bitcoin futures is significantly higher than the proposed limit of 25,000 options contract for the VanEck Bitcoin ETF option. The fact that many options ultimately expire out-of-the-money and thus are not exercised for shares of the underlying, while the delta of a Bitcoin Future is 1, further demonstrates how conservative the proposed limits of 25,000 options contracts are for the VanEck Bitcoin ETF options.

The Exchange notes, unlike options contracts, CME position limits are calculated on a net futures-equivalent basis by contract and include contracts that aggregate into one or more base

contracts according to an aggregation ratio(s).⁴⁵ Therefore, if a portfolio includes positions in options on futures, CME would aggregate those positions into the underlying futures contracts in accordance with a table published by CME on a delta equivalent value for the relevant spot month, subsequent spot month, single month and all month position limits.⁴⁶ If a position exceeds position limits because of an option assignment, CME permits market participants to liquidate the excess position within one business day without being considered in violation of its rules. Additionally, if at the close of trading, a position that includes options exceeds position limits for futures contracts, when evaluated using the delta factors as of that day's close of trading but does not exceed the limits when evaluated using the previous day's delta factors, then the position shall not constitute a position limit violation. Considering CME's position limits on futures for Bitcoin, the Exchange believes that that the proposed same side position limits are

more than appropriate for the VanEck Bitcoin ETF options.

The Exchange believes the proposed position and exercise limits in this proposal will have no material impact to the supply of Bitcoin. For example, consider again the proposed position limit of 25,000 option contracts for the VanEck Bitcoin ETF option. As noted above, a position limit of 25,000 same side contracts effectively restricts a market participant from holding positions that could result in the receipt of no more than 2,500,000 shares of the applicable VanEck Bitcoin ETF (if that market participant exercised all its options). As of March 5, 2025, the VanEck Bitcoin ETF had the number of shares outstanding set forth in the table below. The table below also sets forth the approximate number of market participants that could hold the maximum of 25,000 same side positions in the VanEck Bitcoin ETF that would equate to the number of shares outstanding of the VanEck Bitcoin:

Bitcoin fund	Shares outstanding	Number of market participants with 25,000 same side positions
VanEck Bitcoin ETF	49,900,000	20

This means if 20 market participants had 25,000 same side positions in VanEck Bitcoin ETF options, each of them would have to simultaneously exercise all of those options to create a scenario that may put the underlying security under stress. The Exchange believes it is highly unlikely for either such event to occur; however, even if either such event did occur, the Exchange would not expect the VanEck Bitcoin ETF to be under stress because such an event would merely induce the creation of more shares through the trust's creation and redemption process.

As of March 5, 2025, the global supply of Bitcoin was approximately 19,832,309.⁴⁷ Based on the \$25.60 price of VanEck Bitcoin ETF share on March 5, 2025, a market participant could have redeemed one Bitcoin for approximately 3,539 VanEck Bitcoin ETF shares. Another 70,194,417,201 VanEck Bitcoin

ETF shares could be created before the supply of Bitcoin was exhausted. As a result, 28,078 market participants would have to simultaneously exercise 25,000 same side positions in VanEck Bitcoin ETF options to receive shares of the VanEck Bitcoin ETF holding the entire global supply of Bitcoin. Unlike the VanEck Bitcoin ETF, the number of shares that corporations may issue is limited. However, like corporations, which authorize additional shares, repurchase shares, or split their shares, the VanEck Bitcoin ETF may create, redeem, or split shares in response to demand. While the supply of Bitcoin is limited to 21,000,000, it is believed that it will take more than 100 years to fully mine the remaining Bitcoin. The supply of Bitcoin is larger than the available supply of most securities.⁴⁸ Given the significant unlikelihood of any of these events ever occurring, the Exchange

does not believe options on the VanEck Bitcoin ETF should be subject to position and exercise limits even lower than those proposed (which are already equal to the lowest available limit for equity options in the industry) to protect the supply of Bitcoin.⁴⁹

The Exchange believes the available supply of Bitcoin is not relevant to the determination of position and exercise limits for options overlying the VanEck Bitcoin ETF. Position and exercise limits are not a tool that should be used to address a potential limited supply of the underlying of an underlying. Position and exercise limits do not limit the total number of options that may be held, but rather they limit the number of positions a single customer may hold or exercise at one time.⁵⁰ "Since the inception of standardized options trading, the options exchanges have had rules imposing limits on the aggregate

⁴⁵ See CME Rulebook Chapter 5, Position Limit, Position Accountability and Reportable Level Table in the Interpretations & Special Notices.

⁴⁶ *Id.*

⁴⁷ See *Blockchain.com* | Charts—Total Circulating Bitcoin (which also shows the price of one Bitcoin equal to \$90,608.57).

⁴⁸ The market capitalization of Bitcoin would rank in the top 10 among securities. See <https://>

companiesmarketcap.com/usa/largest-companies-in-the-usa-by-market-cap/.

⁴⁹ This would be even more unlikely with respect to the VanEck Bitcoin ETF for which the Exchange proposes lower position limits.

⁵⁰ For example, suppose an option has a position limit of 25,000 option contracts and there are a total of 10 investors trading that option. If all 10 investors max out their positions, that would result

in 250,000 option contracts outstanding at that time. However, suppose 10 more investors decide to begin trading that option and also max out their positions. This would result in 500,000 option contracts outstanding at that time. An increase in the number of investors could cause an increase in outstanding options even if position limits remain unchanged.

number of options contracts that a member or customer could hold or exercise.”⁵¹ Position and exercise limit rules are intended “to prevent the establishment of options positions that can be used or might create incentives to manipulate or disrupt the underlying market so as to benefit the options position. In particular, position and exercise limits are designed to minimize the potential for mini-manipulations and for corners or squeezes of the underlying market. In addition, such limits serve to reduce the possibility for disruption of the options market itself, especially in illiquid options classes.”⁵²

The Exchange notes that a Registration Statement on Form S–1 was filed with the Commission for the VanEck Bitcoin ETF, each of which described the supply of Bitcoin as being limited to 21,000,000 (of which approximately 90% had already been mined), and that the limit would be reached around the year 2140.⁵³ The Registration Statement permits an unlimited number of shares of the applicable the VanEck Bitcoin ETF to be created. Further, the Commission approved proposed rule changes that permitted the listing and trading of shares of the VanEck Bitcoin ETF, which approval did not comment on the sufficient supply of Bitcoin or address whether there was a risk that permitting an unlimited number of shares for the VanEck Bitcoin ETF would impact the supply of Bitcoin.⁵⁴ Therefore, the Exchange believes the Commission had ample time and opportunity to consider whether the supply of Bitcoin was sufficient to permit the creation of unlimited the VanEck Bitcoin ETF shares, and does not believe considering this supply with respect to the establishment of position and exercise limits is appropriate given its lack of relevance to the purpose of position and exercise limits. However, given the significant size of the Bitcoin supply, the proposed positions limits are more than sufficient to protect investors and the market.

Based on the above information demonstrating, among other things, that the VanEck Bitcoin ETF is characterized by a substantial number of outstanding shares that are actively traded and widely held, the Exchange believes the proposed position and exercise limits are extremely conservative compared to those of ETF options with similar

market characteristics. The proposed position and exercise limits reasonably and appropriately balance the liquidity provisioning in the market against the prevention of manipulation. The Exchange believes these proposed limits are effectively designed to prevent an individual customer or entity from establishing options positions that could be used to manipulate the market of the underlying as well as the Bitcoin market.⁵⁵

The Exchange represents that it has the necessary systems capacity to support VanEck Bitcoin ETF options. As discussed above, the Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might arise from listing and trading Unit options, including VanEck Bitcoin ETF options.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as the VanEck Bitcoin ETF will be equally available to all market participants who wish to trade such options and will trade generally in the same manner as other options. The Exchange Rules that currently apply to the listing and trading of all Unit options on the Exchange, including, for example, Rules that govern listing criteria, expirations, exercise prices, minimum increments, margin requirements, customer accounts, and trading halt procedures will apply to the listing and trading of the VanEck Bitcoin ETF options on the Exchange in the same manner as they apply to other options on all other Units that are listed and traded on the Exchange. Also, and as stated above, the Exchange already lists options on other commodity-based Units.⁵⁶ Further, the VanEck Bitcoin ETF would need to satisfy the maintenance listing standards set forth in the Exchange Rules in the same manner as any other Unit for the Exchange to continue listing options on them.

The Exchange does not believe that the proposal to list and trade options on

the VanEck Bitcoin ETF will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the extent that the advent of the VanEck Bitcoin ETF options trading on the Exchange may make the Exchange a more attractive marketplace to market participants at other exchanges, such market participants are free to elect to become market participants on the Exchange. Additionally, other options exchanges are free to amend their listing rules, as applicable, to permit them to list and trade options on the VanEck Bitcoin ETF. The Exchange notes that listing and trading VanEck Bitcoin ETF options on the Exchange will subject such options to transparent exchange-based rules as well as price discovery and liquidity, as opposed to alternatively trading such options in the OTC market.

The Exchange believes that the proposed rule change may relieve any burden on, or otherwise promote, competition, as it is designed to increase competition for order flow on the Exchange in a manner that is beneficial to investors by providing them with a lower-cost option to hedge their investment portfolios. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues that offer similar products. Ultimately, the Exchange believes that offering VanEck Bitcoin ETF options for trading on the Exchange will promote competition by providing investors with an additional, relatively low-cost means to hedge their portfolios and meet their investment needs in connection with Bitcoin prices and Bitcoin-related products and positions on a listed options exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received written comments on the proposed rule change.

III. Proceedings To Determine Whether To Approve or Disapprove SR–CBOE–2025–017, as Modified by Amendment No. 4, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act⁵⁷ to determine whether the proposed rule change, as modified by Amendment No. 4, should be approved or disapproved. Institution of such proceedings is appropriate at

⁵¹ See Securities Exchange Act Release No. 39489 (December 24, 1997), 63 FR 276 (January 5, 1998) (SR–CBOE–1997–11).

⁵² See *id.*

⁵³ See Amendment No. 8 to Form S–1 Registration Statement No. 333–251808, filed January 9, 2024.

⁵⁴ See Bitcoin ETP Approval Order.

⁵⁵ See Securities Exchange Act Release No. 39489 (December 24, 1997), 63 FR 276 (January 5, 1998) (SR–CBOE–1997–11).

⁵⁶ See Rule 4.3, Interpretation and Policy .06(a)(4).

⁵⁷ 15 U.S.C. 78s(b)(2)(B).

this time in view of the legal and policy issues raised by the proposed rule change, as modified by Amendment No. 4. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change, as modified by Amendment No. 4.

Pursuant to Section 19(b)(2)(B) of the Act,⁵⁸ the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposal's consistency with Section 6(b)(5) of the Act,⁵⁹ 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 protect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Under the Commission's Rules of Practice, the "burden to demonstrate that a proposed rule change is consistent with the [Act] and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change."⁶⁰ 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,⁶¹ 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 Act and the applicable rules and regulations.⁶² The Commission is instituting proceedings to allow for additional consideration and comment on the issues raised herein, including as to whether the proposal, as modified by Amendment No. 4, is consistent with the Act. In particular, the Commission asks commenters to address whether the proposal, as modified by Amendment No. 4, includes sufficient data and analysis to support a conclusion that the proposal, as modified by Amendment No. 4, is consistent with the

requirements of Section 6(b)(5) of the Act.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal, as modified by Amendment No. 4. In particular, the Commission invites the written views of interested persons concerning whether the proposal, as modified by Amendment No. 4, is consistent with Section 6(b)(5) or any other provision of the Act, and 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 views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4 under the Act,⁶³ any request for an opportunity to make an oral presentation.⁶⁴

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change, as modified by Amendment No. 4, should be approved or disapproved by July 23, 2025. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by August 6, 2025.

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-CBOE-2025-017 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-CBOE-2025-017. This file number should be included on the subject line if email is used. To help the Commission process and review your

⁶³ 17 CFR 240.19b-4.

⁶⁴ Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94-29 (June 4, 1975), grants 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).

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-CBOE-2025-017 and should be submitted on or before July 23, 2025. Rebuttal comments should be submitted by August 6, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶⁵

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-12300 Filed 7-1-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0047]

Submission for OMB Review; Comment Request; Extension: Rule 204-3

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget a request for extension of the previously

⁶⁵ 17 CFR 200.30-3(a)(57).

⁵⁸ See *id.*

⁵⁹ 15 U.S.C. 78f(b)(5).

⁶⁰ 17 CFR 201.700(b)(3).

⁶¹ See *id.*

⁶² See *id.*

approved collection of information discussed below.

The title for the collection of information is “Rule 204–3 (17 CFR 275.204–3) under the Investment Advisers Act of 1940.” (15 U.S.C. 80b). Rule 204–3, the “brochure rule,” requires advisers to deliver their brochures and brochure supplements at the start of an advisory relationship and to deliver annually thereafter the full updated brochures or a summary of material changes to their brochures. The rule also requires that advisers deliver amended brochures or brochure supplements (or just a statement describing the amendments) to clients only when disciplinary information in the brochures or supplements becomes materially inaccurate.

The brochure assists the client in determining whether to retain, or continue employing, the adviser. The information that rule 204–3 requires to be contained in the brochure is also used by the Commission and staff in its enforcement, regulatory, and examination programs. This collection of information is found at 17 CFR 275.204–3 and is mandatory.

The respondents to this information collection are certain investment advisers registered with the Commission. The Commission has estimated that compliance with rule 204–3 imposes a burden of approximately 4.04 hours annually based on advisers having a median of 95 clients each. Our latest data indicate that there were 15,464 advisers registered with the Commission as of March 31, 2024. Based on this figure, the Commission estimates a total annual burden of 62,525 hours for this collection of information.

Rule 204–3 does not require recordkeeping or record retention. The collection of information requirements under the rule are mandatory. The information collected pursuant to the rule is not filed with the Commission, but rather takes the form of disclosures to clients and prospective clients. Accordingly, these disclosures are not kept confidential. 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 control number.

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.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will

have practical utility; (b) the accuracy of the SEC’s estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

The public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202504-3235-005 or email comment to MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov within 30 days of the day after publication of this notice, by August 4, 2025.

Dated: June 30, 2025.

J. Matthew DeLesDernier,
Deputy Secretary.

[FR Doc. 2025–12394 Filed 7–1–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103343; File No. SR–ISE–2025–15]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend the Short Term Option Series Program To List Qualifying Securities

June 27, 2025.

On May 1, 2025, Nasdaq ISE, LLC (“Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder, ² a proposed rule change to amend the Exchange’s Short Term Option Series Program to permit the listing of up to two Monday and Wednesday expirations for options on certain individual stocks or Exchange-Traded Fund Shares. The proposed rule change was published for comment in the **Federal Register** on May 21, 2025. ³

Section 19(b)(2) of the Act ⁴ provides that, within 45 days of the publication of notice of the filing of a proposed rule

change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is July 5, 2025. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act, ⁵ designates August 19, 2025, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–ISE–2025–15).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. ⁶

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025–12302 Filed 7–1–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35662]

Deregistration Under Section 8(f) of the Investment Company Act of 1940

June 27, 2025.

AGENCY: Securities and Exchange Commission (“Commission” or “SEC”).

ACTION: Notice of Applications for Deregistration under Section 8(f) of the Investment Company Act of 1940.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of June 2025. A copy of each application may be obtained via the Commission’s website by searching for the applicable file number listed below, or for an applicant using the Company name search field, on the SEC’s EDGAR system. The SEC’s EDGAR system may be searched at <https://www.sec.gov/edgar/searchedgar/companysearch.html>. You may also call

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 103048 (May 15, 2025), 90 FR 21805. Comments on the proposed rule change are available at <https://www.sec.gov/comments/sr-ise-2025-15/srise202515.htm>.

⁴ 15 U.S.C. 78s(b)(2).

⁵ *Id.*

⁶ 17 CFR 200.30–3(a)(31).

the SEC's Office of Investor Education and Advocacy at (202) 551-8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretaries-Office@sec.gov* and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below. Hearing requests should be received by the SEC by 5:30 p.m. on July 22, 2025, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0-5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary at *Secretaries-Office@sec.gov*.

ADDRESSES: The Commission:
Secretaries-Office@sec.gov.

FOR FURTHER INFORMATION CONTACT: Shawn Davis, Assistant Director, at (202) 551-6413 or Chief Counsel's Office at (202) 551-6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE, Washington, DC 20549-8010.

Cross Shore Discovery Fund [File No. 811-22976]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On February 3, 2025 and May 16, 2025, applicant made liquidating distributions to its shareholders based on net asset value. No expenses were incurred in connection with the liquidation.

Filing Dates: The application was filed on May 21, 2025 and amended on June 24, 2025.

Applicant's Address: 225 Pictoria Drive, Suite 450, Cincinnati, Ohio 45246.

DWS Strategic Municipal Income Trust [File No. 811-05767]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On October 17, 2024, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of \$11,097.50 incurred in connection with the liquidation were paid by the applicant.

Filing Date: The application was filed on May 28, 2025.

Applicant's Address: 875 Third Avenue, New York, New York 10022-6225.

Hartford HLS Series Fund II INC [File No. 811-04615]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Hartford Small Cap Growth HLS Fund a series of Hartford Series Fund, Inc., and on April 29, 2024 made a final distribution to its shareholders based on net asset value. Expenses of \$31,840 incurred in connection with the reorganization were paid by the acquiring fund.

Filing Date: The application was filed on June 13, 2025.

Applicant's Address: 690 Lee Road, Wayne, Pennsylvania 19087.

NB Private Markets Fund III (Master) LLC [File No. 811-22816]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On June 9, 2025, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of \$5,000 incurred in connection with the liquidation were paid by the applicant. Applicant also has retained approximately \$55,987 for the purpose of paying outstanding liabilities.

Filing Date: The application was filed on June 16, 2025.

Applicant's Address: 325 North Saint Paul Street, 49th Floor, Dallas, Texas 75201.

NB Private Markets Fund III (TE) LLC [File No. 811-22815]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On June 9, 2025, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of \$1,500 incurred in connection with the liquidation were paid by the applicant. Applicant also has retained approximately \$26,639 for the purpose of paying outstanding liabilities.

Filing Date: The application was filed on June 16, 2025.

Applicant's Address: 325 North Saint Paul Street, 49th Floor, Dallas, Texas 75201.

NB Private Markets Fund III (TI) LLC [File No. 811-22814]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an

investment company. On June 9, 2025, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of \$1,500 incurred in connection with the liquidation were paid by the applicant. Applicant also has retained approximately \$27,151 for the purpose of paying outstanding liabilities.

Filing Date: The application was filed on June 16, 2025.

Applicant's Address: 325 North Saint Paul Street, 49th Floor, Dallas, Texas 75201.

Security Equity Separate Account 26 [File No. 811-08888]

Summary: Applicant, a unit investment trust, seeks an order declaring that it has ceased to be an investment company. On May 27, 2022, applicant made a liquidating distribution to its shareholders based on net asset value. Expenses of \$6,000 incurred in connection with the liquidation were paid by the depositor of the applicant.

Filing Dates: The application was filed on June 28, 2023 and amended on June 23, 2025.

Applicant's Address: Metropolitan Life Insurance Company, 200 Park Avenue, New York, New York 10166.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-12293 Filed 7-1-25; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21168 and #21169; KANSAS Disaster Number KS-20022]

Administrative Declaration of a Disaster for the State of Kansas

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Kansas dated June 27, 2025.

Incident: Severe Storms, Torrential Rain and Flooding.

DATES: Issued on June 27, 2025.

Incident Period: June 3, 2025, through June 7, 2025.

Physical Loan Application Deadline Date: August 26, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: March 27, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, 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, 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.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Butler.

Contiguous Counties:

Kansas: Chase, Cowley, Elk, Greenwood, Harvey, Marion, Sedgwick, Sumner.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	5.625
Homeowners without Credit Available Elsewhere	2.813
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	3.625
Non-Profit Organizations without Credit Available Elsewhere	3.625
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 211686 and for economic injury is 211690.

The State which received an EIDL Declaration is Kansas.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery and Resilience.

[FR Doc. 2025-12387 Filed 7-1-25; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21167; CALIFORNIA Disaster Number CA-20034 Declaration of Economic Injury]

Administrative Declaration of an Economic Injury Disaster for the State of California

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the State of California dated June 27, 2025.

Incident: Los Angeles County Civil Unrest.

DATES: Issued on June 27, 2025.

Incident Period: June 6, 2025, through June 18, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: March 27, 2026.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, 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, as a result of the Administrator's EIDL declaration, 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.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Los Angeles.

Contiguous Counties:

California: Kern, Orange, San Bernardino, Ventura.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for economic injury is 211670.

The State which received an EIDL Declaration is California.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery and Resilience.

[FR Doc. 2025-12380 Filed 7-1-25; 8:45 am]

BILLING CODE 8026-09-P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA-2025-0036]

Agency Information Collection Activities: Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104-13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes a revision of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA.

(SSA) Social Security Administration, OLCA, Attn: Reports Clearance Director, Mail Stop 3253 Altmeyer, 6401 Security Blvd., Baltimore, MD 21235, Fax: 833-410-1631, Email address: OR.Reports.Clearance@ssa.gov.

Or you may submit your comments online through <https://www.reginfo.gov/public/do/PRAMain> by clicking on Currently under Review—Open for Public Comments and choosing to click on one of SSA's published items. Please reference Docket ID Number [SSA-2025-0036] in your submitted response.

SSA submitted the information collection below to OMB for clearance.

Your comments regarding this information collection would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than August 1, 2025. Individuals can obtain copies of these OMB clearance packages by writing to the OR.Reports.Clearance@ssa.gov.

Supportive Housing & Individual Placement and Support (SHIPS) Study—0960–0840

Background

Homelessness and unemployment are linked issues, with rising housing costs often leaving people unable to afford homes when combined with unemployment. The instability of housing makes finding employment even more challenging, creating a difficult cycle to break.

While studies have shown that supportive housing programs improve housing stability, there is no significant evidence that such programs reliably increase employment among residents. (For the purposes of this study, supportive housing is defined as housing services coupled with additional services that include case management support. These include place-based permanent supportive housing, scattered site permanent supportive housing, and rapid rehousing. Conversely, Individual Placement and Support (IPS), a proven method for supporting employment, has not demonstrated effectiveness in stabilizing housing. SSA is requesting clearance to collect data for the Supportive Housing and Individual Placement and Support (SHIPS) study, under the Interventional Cooperative Agreement Program (ICAP), to determine whether participation in Individual Placement and Support (IPS) improves the employment, income, health, and self-sufficiency of people who are recently homeless and living in supportive housing. ICAP allows SSA to partner with various non-federal groups and organizations to advance interventional research connected to the Supplemental Security Income (SSI) and Social Security Disability Insurance (SSDI) programs. SSA awarded Westat a cooperative agreement to conduct SHIPS. In addition to SSA, Westat is

partnering with three subrecipients for this project: (1) People Assisting the Homeless (PATH), (2) the University of Southern California (U.S.C.), and (3) the Research Foundation for Mental Hygiene (RFMH) to implement the SHIPS study.

ICAP SHIPS Study Project Description

The SHIPS study is a randomized controlled trial (RCT) designed to determine whether participation in Individual Placement and Support (IPS) improves the employment, income, health, and self-sufficiency of people who are recently homeless and living in supportive housing. The SHIPS study will mark the first study testing the effectiveness of implementing IPS in a supportive housing program. SSA hypothesizes that combining the two successful evidence-based practices that separately address homelessness and supported employment will yield a single intervention that effectively addresses both. The intent of the SHIPS study is to measure the effectiveness of evidence-based IPS compared to the services provided by local WorkSource Centers broadly available to jobseekers in the Los Angeles area. The housing case managers will refer PATH clients interested in finding employment and will randomly assign participants to one of two groups:

- **IPS:** The Individual Placement and Support (IPS) service team will offer a range of structured services customized to participants' personal needs, preferences, and challenges related to disabilities and/or mental health conditions. IPS was specifically designed as a supported employment model for individuals with serious mental illness and includes standardized training and fidelity requirements. Components of IPS that differ from those offered by WorkSource Services include integrated treatment that incorporates vocational and mental

health services; benefits planning; and focus on rapid job search without extensive training.

- **WorkSource Centers:** Under PATH's current housing model, housing case managers refer PATH clients who express interest in finding employment to local American Job Centers, known as WorkSource Centers in Los Angeles. The WorkSource Centers are operated by the City of Los Angeles Economic and Workforce Development Department, and follow an employment services model that varies by WorkSource Center, is not evidence-based or subject to fidelity monitoring, and is not necessarily responsive to the individual needs of jobseekers with disabilities.

The primary goals of the SHIPS study are:

- To measure the effects of IPS participation on employment, income, health, and long-term self-sufficiency measured as a combination of housing stability, income, and receipt of DI and SSI benefits.
- To describe the study population in order to understand both the generalizability of the study's findings and the potential reasons for the observed effects.
- To explore the IPS implementation process to understand barriers and facilitators to high-fidelity IPS implementation in the supportive housing context.

Grantee researchers and SSA will use the information collected during this study to (1) assess the short-term and long-term effectiveness of the proposed intervention to improve employment, income, and self-sufficiency; (2) understand the implementation process; (3) provide detailed subgroup-specific data related to the effect of IPS.

The respondents are residents in supportive housing units operated by PATH who are unemployed and looking for employment.

Modality of completion	Number of participants	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars)*	Average wait time in office or for teleservice centers (minutes)**	Total annual opportunity cost (dollars)***
Study participants baseline interview	200	1	200	60	200	* \$13.30	** 23	*** \$3,684
Study participants quarterly interviews	200	7	1,400	10	233	* 13.30	** 102	*** 34,753
Study participants final interviews	200	1	200	60	200	* 13.30	** 102	*** 7,182
PATH Interviews: Staff	5	1	5	60	5	* 35.32	** 23	*** 247
SHIPS Interviews: participants	5	1	5	60	5	* 13.30	** 23	*** 93
Totals	610			250	643			*** 45,959

*We based this figure on the average DI payments based on SSA's current FY 2025 data (<https://www.ssa.gov/legislation/2024FactSheet.pdf>), and survey researchers (Occupational Employment and Wage Statistics).

**We based this figure on averaging both the average FY 2025 wait times for field offices and teleservice centers, as well as on the field office wait times based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

Dated: June 27, 2025.

Mark Steffensen,

General Counsel, Deputy Commissioner for Law and Policy, Social Security Administration.

[FR Doc. 2025-12294 Filed 7-1-25; 8:45 am]

BILLING CODE 4191-02-P

DEPARTMENT OF STATE

[Public Notice: 12751; No. 2025-03]

Determination Pursuant to the Foreign Missions Act

Section 209(a) of the Foreign Missions Act, 22 U.S.C. 4301, *et seq.* (“the Act”), authorizes the Secretary of State to make any provision of the Act applicable with respect to “international organizations,” as defined in Section 209(b) of the Act, to the same extent that it is applicable with respect to foreign missions when the Secretary determines that such application is necessary to carry out the policy set forth in section 201(b) of the Act and to further the objectives set forth in section 204(b) of the Act. Such a determination was made by Determination No. FMA-2014-2, dated January 8, 2014. Accordingly, any provision of the Act may be applied to international organizations, to include official missions, other than a U.S. mission, to public international organizations designated as such pursuant to the International Organizations Immunities Act, 22 U.S.C. 288, *et seq.*, (“IOIA”), and the personnel of such a mission.

Pursuant to the authority vested in the Secretary of State under the Act, and delegated pursuant to Department of State Delegation of Authority No. 214 of September 20, 1994, I hereby determine that the application of all provisions of the Act to the personnel of an official mission, other than a U.S. mission, to a public international organization designated as such pursuant to the IOIA encompasses the application of all provisions of the Act to all members of the mission, including when they have been assigned to their position by or otherwise represent an entity that is not recognized by the United States as the government of a foreign State. This is reasonably necessary to facilitate the secure and efficient operation of public international organizations and the official missions to such organizations; to assist in obtaining benefits, privileges, and immunities for these organizations; and to require their

observance of corresponding obligations in accordance with international law.

This is also reasonably necessary to achieve one or more of the purposes set forth in section 204(b) of the Act.

Furthermore, I determine that it is reasonably necessary to achieve one or more of the purposes set forth in section 204(b) of the Act to require members of official missions to public international organizations designated as such pursuant to the IOIA who have been assigned to their position by or otherwise represent entities that are not recognized by the United States as the government of a foreign State to comply with any requirements as may be established by the Director or Deputy Director of the Office of Foreign Missions, including with respect to limitations on travel within the United States, including Ports of Entry/Exit.

Any existing or future determinations, as well as any existing or future requirements established by the Director or Deputy Director of the Office of Foreign Missions, regarding the provision of benefits under the FMA, including those regarding restrictions on travel with the United States, that are generally applicable to “foreign government officials,” “government officials,” “officials,” or other members of official missions to public international organizations designated pursuant to the IOIA, including members of Permanent Missions to the United Nations, shall apply equally to all members of such missions irrespective of whether they have been assigned by or otherwise represent an entity that is not recognized by the United States as the government of a foreign State.

Clifton C. Seagroves,

Director, Acting, Office of Foreign Missions.

[FR Doc. 2025-12344 Filed 7-1-25; 8:45 am]

BILLING CODE 4711-11-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by the California Department of Transportation (Caltrans).

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans, that are final. The actions relate to a proposed highway project on Interstate 280 (PM 4.5/5.3), Interstate 880 (PM 0.0/0.5), and State Route 17 (PM 13.3/13.9) in the City of San Jose, County of Santa Clara, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before December 1, 2025. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Brian Gassner, Environmental Branch Chief, 111 Grand Avenue, Oakland, CA 94612, M-F (8 a.m.–4 p.m.), 510-506-0372, brian.gassner@dot.ca.gov.

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that Caltrans has taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: Interstate 280/Winchester Boulevard Interchange Improvements Project, primarily consisting of (1) modifying the existing I-280/Winchester Boulevard interchange by constructing a new tunnel off-ramp from northbound I-280 to Winchester Boulevard, (2) constructing a new direct connector ramp from northbound SR-17 to northbound I-280, and (3) replacing the existing Monroe Pedestrian Overcrossing. The actions by Caltrans, and the laws under which such actions were taken, are described in the Environmental Assessment with Finding of No Significant Impact (EA/FONSI) for the project, approved on September 4, 2024, and in other documents in the FHWA project records. The EA/FONSI and other project records are available by contacting Caltrans at the address provided above. The EA/FONSI can be

viewed and downloaded from the project website at <https://www.vta.org/projects/i-280winchester-boulevard-interchange-improvements> or viewed at the Bascom Branch of the San Jose Public Library, 1000 S Bascom Avenue, San Jose, CA 95128 in the project area.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4321 *et seq.*
2. Department of Transportation Act of 1966, Section 4(f)
3. Clean Air Act Amendments of 1990 (CAAA)
4. Clean Water Act of 1977 and 1987
5. Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA)
6. Noise Control Act of 1972
7. Endangered Species Act of 1973
8. Executive Order 13112, Invasive Species (February 3, 1999)
9. Migratory Bird Treaty Act of 1918, as amended
10. Executive Order 11988, Floodplain Management (May 24, 1977)
11. Title VI of the Civil Rights Act of 1964, as amended
12. Uniform Relocation Assistance and Real Property Acquisition Act of 1970, as amended
13. National Historic Preservation Act of 1966, as amended (Section 106)

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

(Authority: 23 U.S.C. 139(l)(1))

Antonio Johnson,

Director of Planning, Environmental and Right of Way, Federal Highway Administration, California Division.

[FR Doc. 2025–12320 Filed 7–1–25; 8:45 am]

BILLING CODE 4910-RY-P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Request by Owner or Person Entitled to Payment or Reissue of United States Savings Bonds/Notes Deposited in Safekeeping When Original Custody Receipts Are Not Available

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Request By Owner or Person Entitled to Payment or Reissue of United States Savings Bonds/Notes Deposited in Safekeeping When Original Custody Receipts Are Not Available.

DATES: Written comments should be received on or before September 2, 2025 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or bruce.sharp@fiscal.treasury.gov.

SUPPLEMENTARY INFORMATION:

Title: Request By Owner or Person Entitled to Payment or Reissue of United States Savings Bonds/Notes Deposited in Safekeeping When Original Custody Receipts Are Not Available.

OMB Number: 1530–0024.

Form Number: FS Form 4239.

Abstract: The information is necessary to request payment or reissue of Savings Bonds/Notes held in safekeeping when original safekeeping custody receipts are not available.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 1,400.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 233.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: June 30, 2025.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2025–12355 Filed 7–1–25; 8:45 am]

BILLING CODE 4810-AS-P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Claim for United States Savings Bonds Not Received

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Claim for United States Savings Bonds Not Received.

DATES: Written comments should be received on or before September 2, 2025 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or bruce.sharp@fiscal.treasury.gov.

SUPPLEMENTARY INFORMATION:

Title: Claim for United States Savings Bonds Not Received.

OMB Number: 1530–0048.

Form Number: FS Form 3062–4.

Abstract: The information is used to support a request for relief on account of the nonreceipt of United States Savings Bonds.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 1,000.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 167.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: June 30, 2025.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2025-12358 Filed 7-1-25; 8:45 am]

BILLING CODE 4810-AS-P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Application For Disposition of Retirement Plan and/or Individual Retirement Bonds Without Administration of Deceased Owner's Estate

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Application for Disposition of Retirement Plan and/or Individual Retirement Bonds Without Administration of Deceased Owner's Estate.

DATES: Written comments should be received on or before September 2, 2025 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A.

Sharp, Room #4006-A, P.O. Box 1328, Parkersburg, WV 26106-1328, or bruce.sharp@fiscal.treasury.gov.

SUPPLEMENTARY INFORMATION: *Title:* Application For Disposition of Retirement Plan and/or Individual Retirement Bonds Without Administration of Deceased Owner's Estate.

OMB Number: 1530-0032.

Form Number: FS Form 3565.

Abstract: The information is used to support a request for recognition as a person entitled to United States Retirement Plan and/or Individual Retirement bonds which belonged to a deceased owner when a legal representative has not been appointed for the estate and no such appointment is pending.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 350.

Estimated Time Per Respondent: 20 minutes.

Estimated Total Annual Burden Hours: 117.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (5) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: June 30, 2025.

Bruce A. Sharp,

Bureau PRA Clearance officer.

[FR Doc. 2025-12356 Filed 7-1-25; 8:45 am]

BILLING CODE 4810-AS-P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Regulations Governing U.S. Treasury Securities—State and Local Government Series

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Regulations Governing U.S. Treasury Securities—State and Local Government Series.

DATES: Written comments should be received on or before September 2, 2025 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006-A, P.O. Box 1328, Parkersburg, WV 26106-1328, or bruce.sharp@fiscal.treasury.gov.

SUPPLEMENTARY INFORMATION:

Title: Regulations Governing U.S. Treasury Securities—State and Local Government Series.

OMB Number: 1530-0044.

Abstract: The regulations govern U.S. Treasury bonds, notes and certificates of indebtedness of the States and Local Government Series. The collection of information is necessary to enable Treasury to establish an investor's account, to issue securities, to ensure that an investor meets the certification requirements, to redeem securities either at or prior to maturity, and to obtain necessary documentation where a waiver is involved.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: State or Local or Governments.

Estimated Number of Respondents: 60.

Estimated Time per Respondent: 13 minutes.

Estimated Total Annual Burden Hours: 13.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of

public record. Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (5) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: June 30, 2025

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2025–12357 Filed 7–1–25; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: States Where Licensed for Surety

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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 proposed and/or continuing information

collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the States Where Licensed for Surety.

DATES: Written comments should be received on or before September 2, 2025 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or bruce.sharp@fiscal.treasury.gov.

SUPPLEMENTARY INFORMATION:

Title: States Where Licensed for Surety.

OMB Number: 1530–0009.

Abstract: Information is collected from insurance companies in order to provide Federal bond approving officers with this information. The listing of states, by company, appears in Treasury's Circular 570, "Surety Companies Acceptable on Federal Bonds."

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 264.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 264.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the

request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: June 30, 2025.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2025–12354 Filed 7–1–25; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

United States Mint

Pricing for Comic Art 1 Oz. Silver Medal and 2.5 Oz. Silver Medal

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

The United States Mint is announcing pricing for the 2025 Comic Art Coin and Medal 1 oz. and 2.5 oz. silver medals.

SKU #	Product name	Price
25DSG	Comic Art Half Oz. 24K Gold Proof Coin—Superman	Per Grid.
25DSS1	Comic Art One Oz. Silver Medal—Superman	\$135.00.
25DSS2	Comic Art 2.5 Ounce Silver Medal—Superman	\$275.00.

FOR FURTHER INFORMATION CONTACT: Rosa Williams, United States Mint; 801 9th Street NW, Washington, DC 20220; or call (202) 354–7594.

Authority: 31 U.S.C. 5111(a)(2).

Eric Anderson,

Executive Secretary, United States Mint.

[FR Doc. 2025–12389 Filed 7–1–25; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 414, et al.

Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 414, 424, 455, 484, and 498

[CMS–1828–P]

RIN 0938–AV53

Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).
ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth routine updates to the Medicare home health payment rates in accordance with existing statutory and regulatory requirements. In addition, this proposed rule proposes permanent and temporary behavior adjustments and proposes to recalibrate the case-mix weights and update the functional impairment levels; comorbidity subgroups; and low-utilization payment adjustment (LUPA) thresholds for CY 2026. Lastly, this proposed rule proposes policy changes to the face-to-face encounter policy. It also proposes changes to the Home Health Quality Reporting Program (HH QRP) and the expanded Health Value-Based Purchasing (HHVBP) Model requirements. In addition, it would update the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). Lastly it proposes: a technical change to the HH conditions of participation; updates to DMEPOS supplier conditions of payment; updates to provider and supplier enrollment requirements; and changes to DMEPOS accreditation requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on September 2, 2025.

ADDRESSES: In commenting, please refer to file code CMS–1828–P. Because of staff and resource limitations, we cannot

accept comments by facsimile (FAX) transmission.

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 (and we encourage you to) submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the instructions under the “submit a comment” tab.

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–1828–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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 via express or overnight mail to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1828–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to HomeHealthPolicy@cms.hhs.gov.

For information about the Home Health Quality Reporting Program (HH QRP), send your inquiry via email to HHQRPquestions@cms.hhs.gov.

For more information about the expanded Home Health Value-Based Purchasing Model, please visit the Expanded HHVBP Model web page at <https://www.cms.gov/priorities/innovation/innovation-models/expanded-home-health-value-based-purchasing-model> or send your inquiry via email to HHVBPquestions@cms.hhs.gov.

Frank Whelan (410) 786–1302, for Medicare provider and supplier enrollment and DMEPOS accreditation inquiries.

Katie Parker (410) 786–0537, Emily Calvert (410) 786–4277, or Jessica Martindale (410) 786–1558 for DMEPOS Prior Authorization inquiries.

Alexander Ullman at (410) 786–9671 or DMEPOS@cms.hhs.gov, for DMEPOS Competitive Bidding Program inquiries.

For information about the Home Health Conditions of Participation, send

your inquiry via email to healthandsafetyinquiries@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov/>. Follow the search instructions on that website to view public comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at <https://www.regulations.gov/>.

Deregulation Request for Information (RFI): On January 31, 2025, President Trump issued Executive Order (E.O.) 14192 “Unleashing Prosperity Through Deregulation,” which states the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America’s economic prosperity and national security and the highest possible quality of life for each citizen. We would like public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other stakeholders participating in the Medicare program. CMS has made available a Request for Information (RFI) at: (<https://www.cms.gov/medicare-regulatory-relief-rfi>). Please submit all comments in response to this request for information through the provided weblink.

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I. Executive Summary

A. Purpose and Legal Authority

1. Home Health Prospective Payment System (HH PPS)

As required under section 1895(b) of the Social Security Act (the Act), this proposed rule would update the CY 2026 Medicare payment rates for home health agencies (HHAs). In this proposed rule, we include an analysis of home health utilization, as well as analysis of the difference between assumed versus actual behavior change on estimated aggregate expenditures for home health payments as a result of the change in the unit of payment to 30 days and the implementation of the Patient Driven Groupings Model (PDGM) case-mix adjustment methodology. This rule analyzes the difference between assumed versus actual behavior change on estimated aggregate expenditures and proposes permanent and temporary adjustments to the CY 2026 home health base payment rate. In addition, this rule proposes to recalibrate the PDGM case-mix weights and to update the low-utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups under sections 1895(b)(4)(A)(i) and (b)(4)(B) of the Act

for 30-day periods of care in CY 2026. This proposed rule proposes to update the CY 2026 fixed-dollar loss (FDL) ratio for outlier payments (so that outlier payments as a percentage of estimated total payments are projected not to exceed 2.5 percent, as required by section 1895(b)(5)(A) of the Act). Additionally, this rule proposes changes to the face-to-face encounter policy at 42 CFR 424.22(a)(1)(v) to align with section 3708 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).

2. Home Health (HH) Quality Reporting Program (QRP)

In accordance with the statutory authority at section 1895(b)(3)(B)(v) of the Act, we are proposing updated quality reporting policies. We are proposing to remove the COVID–19 Vaccine: Percent of Patients Who Are Up to Date measure and the item related to the measure and corresponding data element. CMS is proposing the removal of four assessment items: one Living Situation item, two Food items, and one Utilities item. We are also proposing to revise the policy to allow for providers to submit a request for reconsideration of an initial determination of noncompliance if they can demonstrate full compliance. In very limited circumstances, HHAs can request an extension to file a reconsideration request if the HHA was affected by an extraordinary circumstance beyond the control of the HHA (that is, a natural or man-made disaster such as a cyber-attack, hurricane, tornado, or earthquake) during the 30-day reconsideration period. CMS is also proposing to implement a revised Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) Survey beginning with the April 2026 sample month. This rule would also update regulatory text to account for all-payer data submission of OASIS data. We are seeking information on a change to the final data submission deadline period from 4.5 months to 45 days. We are also seeking feedback on the digital quality measurement (dQM) transition for HHAs. We aim to solicit feedback from the public on the current adoption of health information technology (IT) and standards including Fast Healthcare Interoperability Resources (FHIR), including related challenges or barriers HHAs are facing. Finally, we are seeking input on future HH QRP quality measure (QM) concepts of interoperability, cognitive function, nutrition, and patient well-being.

3. Expanded Home Health Value-Based Purchasing (HHVBP) Model

In accordance with the statutory authority at section 1115A of the Act, we are doing the following for the expanded HHVBP Model: (1) proposing a new measure removal factor for the expanded HHVBP Model applicable measure set; (2) proposing changes to the expanded HHVBP Model applicable measure set; and (3) including a request for information (RFI) related to potential future performance measure concepts.

We propose to add a new measure removal factor for the expanded HHVBP Model applicable measure set for measures that are not feasible to implement. We propose to remove three HHCAHPS Survey-based measures, to align with proposed changes to the HHCAHPS survey. We also propose the addition of four new measures. These additions include the claims-based Medicare Spending Per Beneficiary Post-Acute Care (MSPB-PAC) measure, and three OASIS-based function measures: Improvement in Bathing, Improvement in Upper Body Dressing, and Improvement in Lower Body Dressing. Due to these proposed changes to the applicable measure set, we also propose to revise the weights of the individual HHVBP measures as well as the measure categories. We also include an RFI related to potential future measure concepts for the expanded HHVBP Model.

4. Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements

We propose technical regulation text changes to the Home Health Conditions of Participation (CoP). These technical changes update terminology in the Home Health CoPs to further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services.

5. Medicare and Medicaid Provider Enrollment

Consistent with section 1866(j) of the Act, we are proposing several Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include but are not limited to: (1) modifying grounds for denying, revoking, or deactivating a provider's or supplier's Medicare enrollment; and (2) expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers, which we believe would assist in

protecting the Trust Funds and Medicare beneficiaries.

We are also proposing a technical correction to one of our Medicaid provider enrollment provisions in 42 CFR 455.416 to further clarify the scope of § 455.416(c).

6. DMEPOS Supplier Accreditation Organizations

Consistent with provisions in section 1834(a)(20) of the Act, we are proposing to revise and supplement a number of our regulations regarding DMEPOS supplier accreditation and, in particular, requirements that an organization must meet to become and remain a CMS-approved DMEPOS accrediting organization (AO). Our proposed revisions include but are not limited to: (1) requiring DMEPOS suppliers to be surveyed and reaccredited every year (as opposed to the current 3-year cycle); (2) eliminating inconsistencies among AOs in how they oversee DMEPOS suppliers; and (3) strengthening our ability to take action against poorly performing DMEPOS AOs. We believe these changes would help better ensure that DMEPOS AOs closely oversee DMEPOS suppliers for compliance with the DMEPOS quality standards.

7. DMEPOS Prior Authorization

Consistent with provisions in section 1834(a)(15) of the Act and final rule provisions published in the November 8, 2019 **Federal Register** titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements" (84 FR 60648), hereinafter referred to as the "2019 ESRD PPS & DMEPOS final rule," we propose to clarify authority at § 414.234(c)(1)(ii) to exempt compliant suppliers, while also establishing notice guidelines for establishing an exemption and withdrawal of an exemption. The 2019 ESRD PPS & DMEPOS final rule created the authority at § 414.234(c)(1)(ii) to exempt suppliers from required prior authorization of DMEPOS items upon compliance with Medicare coverage, coding, and payment requirements. However, to

clarify this process for exemption from prior authorization requirements, CMS is proposing to establish guidelines for granting and withdrawing exemptions. Furthermore, we are proposing to establish notification requirements to put suppliers on notice that the exemption has either been granted or withdrawn.

8. DMEPOS Competitive Bidding Program

We are proposing changes to regulations at subpart C of 42 CFR 414 we believe are necessary for the effective implementation of the DMEPOS Competitive Bidding Program (CBP) mandated by section 1847(a) of the Act.

a. Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP

The purpose of this proposal is to revise both how single payment amounts (SPAs) are calculated and how CMS determines the number of contracts to award in each "competition," which is a term that we use under the DMEPOS CBP to refer to a competitive bidding area (CBA) and product category combination.

b. Adjustments to SPAs

The purpose of this proposal is to acknowledge the challenge and uncertainty a bidder may face when factoring inflation into its bid. We believe that adding an annual increase to the SPAs to account for inflation would be consistent with Medicare making annual covered item updates for other DMEPOS items and services. This would account for inflation in the cost of doing business for suppliers submitting bids for furnishing items under a multiyear contract.

c. Bid Limits and Conditions for Awarding Contracts if Savings Are Not Expected

The purpose of this proposal is to revise the methodology used to establish bid limits and establish the conditions for determining when contracts cannot be awarded in accordance with section 1847(b)(2)(A)(iii) of the Act because the total amounts to be paid to contract suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. We believe these proposed changes would better ensure the DMEPOS CBP is responsive to rising costs over time while still ensuring alignment with the statutory requirement for achieving savings.

d. Revising the Definition of “Item” Related to Medical Supplies

The purpose of this proposal is to specify that ostomy, tracheostomy, and urological supplies are medical equipment items mandated for inclusion under the DMEPOS CBP by section 1847(a)(2)(A) of the Act.

e. Remote Item Delivery (RID) CBP

The purpose of this proposal is to create two new definitions under § 414.402 for “Remote item delivery CBP” and “Remote item delivery item” for the purpose of establishing one or more RID CBPs wherein contract suppliers would be responsible for furnishing the items and services under the product category primarily on a mail order basis to all Medicare beneficiaries regardless of where they live in the CBA, but could also furnish the items on a non-mail order basis. Any competitively bid item furnished on a non-mail order basis would also need to be furnished by a contract supplier. We are proposing that for a given product category, we could implement one nationwide RID CBP that would include all areas (all States, territories, and the District of Columbia) or we could implement multiple RID CBPs covering different regions of the country. Items included in a nationwide or regional RID CBP would be those that are typically furnished to beneficiaries from remote supplier locations that are hundreds of miles on average from the beneficiary residence where the items are delivered.

f. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

The purpose of this proposal is to make payment under the DMEPOS CBP for certain continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories on a bundled monthly rental basis. The technology of products used by beneficiaries to help manage diabetes continues to change rapidly, and without frequent and substantial servicing to ensure that the devices continue to function correctly, the beneficiary might not receive information they need to make correct diabetes treatment decisions or the dosage of insulin administered by the insulin pump could be incorrect, putting the beneficiary in imminent danger. This proposal would eliminate the need to wait 5 years to replace equipment, allowing beneficiaries to use the latest technologically updated items. Payment for continuous glucose monitors and insulin infusion pumps and all necessary supplies and

accessories that are not furnished under the DMEPOS CBP would also be made on a bundled monthly rental basis in the same amounts established for continuous glucose monitors and insulin infusion pumps under the DMEPOS CBP.

g. Revising the Submission of Financial Documents for the DMEPOS CBP

The purpose of this proposal is to streamline the requirements and evaluation of the DMEPOS CBP financial standards, while still ensuring that suppliers that are offered contracts are financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period.

h. Revising the Covered Document Review Date Evaluation and Notification Process for the DMEPOS CBP

The purpose of this proposal is to streamline the process for evaluating and notifying a bidder who submitted a covered document by the covered document review date if a covered document(s) is missing.

i. Bid Surety Bond Review Process

The purpose of this proposal is to codify the bid surety bond rider process that occurred during the DMEPOS CBP round in 2021 and to correct a regulatory citation error from previous rulemaking.

j. Tribal Exemption From Participating in the DMEPOS CBP

The purpose of this proposal is to add a Tribal exception to the DMEPOS CBP regulations.

k. Addition of a Termination Clause for the DMEPOS CBP Supplier Contracts

The purpose of this proposal is to add a termination clause to the DMEPOS CBP contracts that could be utilized during a public health emergency (PHE), when CMS determines that credible evidence exists of an access problem for beneficiaries, and when CMS believes the termination of an entire DMEPOS CBP contract, the termination of a competition on a DMEPOS CBP contract, or the termination of a defined area(s) within a CBA could improve the situation for the applicable competition(s) or defined areas (for example, ZIP codes) within a CBA.

l. Technical Change to § 414.408(h)(8)

The purpose of this proposal is to make a technical change to § 414.408(h)(8) so that it correctly refers to paragraph (h)(8)(ii) instead of paragraph (h)(7)(ii).

m. Adding Definitions of Adjusted Fee Schedule, Amount Competition, and Unadjusted Fee Schedule Amount to § 414.402

The purpose of this proposal is to add definitions of “Adjusted fee schedule amount,” “Competition,” and “Unadjusted fee schedule amount” to § 414.402 for the purpose of simplifying the regulation text for subpart F.

B. Summary of the Provisions of This Proposed Rule

1. Home Health Prospective Payment System (HH PPS)

In section II.B.1. of this proposed rule, we provide monitoring and data analysis on the PDGM utilization.

In section II.C.1. of this proposed rule, we propose a permanent adjustment and a temporary adjustment to the base payment rate under the HH PPS.

In section II.D. of this proposed rule, we propose to recalibrate the CY 2026 PDGM case-mix weights and to update the low-utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups.

In section II.E. of this proposed rule, we propose to update the home health wage index. We also propose to update the CY 2026 national, standardized 30-day period payment rates and the CY 2026 national per-visit payment amounts by the home health payment update percentage. The proposed home health payment update percentage for CY 2026 is 2.4 percent. Additionally, this rule proposes the CY 2026 fixed dollar loss (FDL) ratio to ensure that aggregate outlier payments are projected not to exceed 2.5 percent of the total aggregate payments, as required by section 1895(b)(5)(A) of the Act.

In section II.F. of this proposed rule, we propose changes to the face-to-face encounter policy at 42 CFR 424.22(a)(1)(v).

2. Home Health Quality Reporting Program (HH QRP)

In section III. of this proposed rule, we are proposing to remove the COVID-19 Vaccine: Percent of Patients Who Are Up to Date measure and the item related to the measure. CMS is proposing the removal of four assessment items: one Living Situation item, two Food items, and one Utilities item. CMS is also proposing to implement a revised HHCAHPS Survey beginning with the April 2026 sample month. We are also proposing to revise the policy to allow for providers to submit a request for reconsideration of an initial determination of non-compliance with the HH QRP data submission

requirements. They can request this if they believe that they can demonstrate full compliance. We are also proposing that, in very limited circumstances, the HHA could request an extension to file a reconsideration request if the HHA was affected by an extraordinary circumstance beyond the control of the HHA, (that is, a natural disaster or man-made disaster such as a cyber-attack, hurricane, tornado, or earthquake) during the 30-day period for requesting reconsideration of the initial determination. We are also seeking information on a change to the final data submission deadline period from 4.5 months to 45 days. We are also seeking feedback on the digital quality measurement (dQM) transition for HHAs. We aim to solicit feedback from the public on current adoption of health information technology (IT) and standards, including Fast Healthcare Interoperability Resources (FHIR), and what related challenges or barriers HHAs are facing. Finally, we are seeking input on future HH QRP quality measure (QM) concepts of interoperability, cognitive function, nutrition, and patient well-being.

3. Expanded Home Health Value Based Purchasing (HHVBP) Model

In section IV. of this proposed rule, we propose to add a new measure removal factor for the expanded HHVBP Model applicable measure set. This ninth measure removal factor would allow CMS to propose removal of a measure when it is no longer feasible to implement the measure specifications. We also propose changes to the expanded HHVBP Model applicable measure set and changes to measure weights. We propose to remove three HHCAHPS Survey-based measures, to align with proposed changes to the HHCAHPS survey. We also propose the addition of four new measures. These additions include the claims-based Medicare Spending Per Beneficiary Post-Acute Care (MSPB-PAC) measure, and three OASIS-based function measures: Improvement in Bathing, Improvement in Upper Body Dressing, and Improvement in Lower Body Dressing. Due to these proposed changes to the applicable measure set, we also propose to revise the weights of the individual HHVBP measures and the measure categories.

We also include an RFI related to potential future measure concepts for the expanded HHVBP Model.

4. Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements

In section V. of this proposed rule, we propose technical regulation text changes to the Home Health Conditions of Participation (CoP) to align with the OASIS all-payer submission requirements. These technical changes update terminology in the Home Health CoPs to further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services.

5. Medicare and Medicaid Provider Enrollment

We are proposing several Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include, but are not limited to, the following:

- Modifying grounds for denying, revoking, or deactivating a provider's or supplier's Medicare enrollment.
- Expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations.
- Expanding the reasons for which CMS can apply a stay of enrollment.
- Requiring providers and suppliers to report any adverse legal actions imposed against them, their owners, their managers, etc. within 30 days instead of the current 90 days.

We believe these revisions would help keep unqualified providers and suppliers out of the Medicare program, which, in turn would prevent improper Medicare payments to such parties.

6. DMEPOS Supplier Accreditation Organizations

DMEPOS suppliers are required to be accredited by a CMS-approved accrediting organization to enroll in and bill Medicare. The purpose of accreditation is to confirm, typically through an on-site survey of the supplier, that the supplier meets the DMEPOS quality standards. Regulations promulgating our accreditation requirements were enacted in 2006 but have not been updated since then. We are concerned there may be instances where: (1) AOs are accrediting DMEPOS suppliers that do not meet the quality standards; and (2) DMEPOS suppliers are falling out of compliance with the quality standards (sometimes for extended periods) after becoming accredited. To enhance our ability to ensure that AOs are performing DMEPOS accreditation functions effectively and thoroughly, including verifying suppliers' compliance with the

quality standards, we are proposing to add a number of provisions to our DMEPOS accreditation regulations. Among our proposed provisions are:

- Requiring DMEPOS suppliers to be surveyed and reaccredited every year (as opposed to the current 3-year cycle).
- Reducing inconsistencies among AOs in how they oversee DMEPOS suppliers.
- Requiring AOs to furnish more detailed information to CMS when applying or reapplying for approval to become or remain a DMEPOS AO.
- Facilitating greater CMS oversight of the DMEPOS AOs.

We believe these and other changes to the DMEPOS accreditation process would help ensure that unqualified DMEPOS suppliers are not accredited and do not, in turn, receive Medicare payments.

7. DMEPOS Prior Authorization

In section V.C. of this proposed rule, we propose to establish guidelines for granting and withdrawing exemptions from mandatory prior authorization requirements for certain DMEPOS suppliers.

8. DMEPOS Competitive Bidding

a. Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP

Currently SPAs for the lead item (defined under § 414.402 as the item in the product category with the highest total allowed charges nationwide) are calculated using the maximum winning bid submitted by bidders whose composite bids for the product category that includes the lead item are equal to or below the pivotal bid for that product category. We are proposing to revise this calculation to use the 75th percentile of winning bids for the lead item by bidders whose composite bids for the product category that includes the lead item are equal to or below the pivotal bid for that product category. We are also proposing to change the way the SPAs are calculated for the non-lead items in a product category in certain CBAs. Currently, the ratio multiplied by the SPA for the lead item to calculate the SPA for the non-lead item is based on the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, and the United States Virgin Islands) for the non-lead item divided by the average of the 2015 fee schedule amounts for all areas for the lead item. This formula uses average fee schedule amounts rather than fee schedule amounts for specific areas, which results in cases where the SPA for a

non-lead item can be higher than the fee schedule amount that would otherwise be paid. To address this situation in CBAs other than remote item delivery CBAs, we are proposing to calculate the ratio based on the 2015 fee schedule amounts for each specific area rather than the average of the 2015 fee schedule amounts for all areas.

Additionally, the proposed rule would revise how CMS determines the number of DMEPOS CBP contracts to award to DMEPOS suppliers by using contract supplier utilization information from previous rounds of the DMEPOS CBP for product categories previously included under the CBP as well as information on current supplier utilization for new product categories.

b. Adjustments to SPAs

We are proposing to apply an annual update factor to SPAs, starting with year two of the DMEPOS CBP contracts.

c. Bid Limits and Conditions for Awarding Contracts if Savings Are Not Expected

We are proposing to amend 42 CFR 414.414(f) so contracts could be awarded in a CBA if the amounts to be paid are no greater than 110 percent of the amounts that would otherwise be paid for the items. This rule clarifies that the amounts that would otherwise be paid include payment amounts adjusted in accordance with § 414.210(g). This rule also proposes to modify 42 CFR 414.412(b) to establish bid limits both for items included in the CBP for the first time and for items that have previously been included in the CBP. For items included in the CBP for the first time, the bid limits would be the amounts otherwise paid for the items. For items that have previously been included in the CBP, the bid limits would be the most recent SPA for the items plus 10 percent, or if it has been more than a year since the SPA was last in effect, the inflation-adjusted SPA plus 10 percent. However, we are proposing that in no event would the bid limit be allowed to exceed the unadjusted fee schedule amount. In addition, this rule proposes a technical correction to add reference to subpart Q ("Payment for Lymphedema Compression Treatment Items") to 42 CFR 414.414(f).

d. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

We are proposing to make payment under the DMEPOS CBP for certain continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories on a bundled monthly rental basis. We are

proposing that payment for continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories that are not furnished under the DMEPOS CBP would also be made on a bundled monthly rental basis with payments limited to the amounts established for continuous glucose monitors and insulin infusion pumps under the DMEPOS CBP.

e. Revising the Definition of "Item" as Related to Medical Supplies

We are proposing to revise the definition of "item" at § 414.402 to clarify that section 1847(a)(2) of the Act includes ostomy, tracheostomy, and urological supplies as "items" subject to the DMEPOS CBP. We are proposing that "medical supplies" under this section is a category of items separate from durable medical equipment that includes ostomy, tracheostomy, and urological supplies.

f. Remote Item Delivery (RID) CBP

We are proposing to create two new definitions under § 414.402 for the purpose of establishing a RID CBP(s) wherein contract suppliers would be required to furnish the items primarily on a mail order basis under the product category to all Medicare beneficiaries regardless of where they live in the CBA. While we expect that the majority of items would be furnished on a mail order basis, a RID competition would not exclude items in the product category that are furnished on a non-mail order basis. Items included in a RID CBP would be those that are typically furnished to beneficiaries from remote supplier locations that are hundreds of miles on average from the beneficiary residence where the items are delivered.

g. Revising the Submission of Financial Document Requirements for the DMEPOS CBP

We are proposing to no longer require the submission of a tax return extract, income statement, balance sheet, or statement of cash flows for the purpose of implementing the financial standards mandated by section 1847(b)(2)(A)(ii) of the Act. This proposal would reduce burden for suppliers submitting bids under the DMEPOS CBP. However, we are proposing to continue requiring suppliers to submit a credit report with a numerical credit score and/or rating from one of the four approved credit reporting agencies during the bid window, and by the CDRD if the supplier wants to be eligible for the process for reviewing covered documents. Additionally, we are proposing to continue using a five-tier

scoring system in the evaluation of the credit report with a numerical credit score and/or rating, which will be utilized to establish a financial score that will indicate if a supplier is financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. We are also proposing to no longer use a supplier's financial score to assist in determining the capacity to assign to each supplier to meet projected beneficiary demand. Furthermore, we are proposing to have suppliers attest to the fact that they meet the small supplier threshold in the DMEPOS Bidding System (DBidS), or any successor system, if applicable.

h. Revising the CDRD Evaluation and Notification Process for the DMEPOS CBP

Since the inception of the DMEPOS CBP, when a bidder has submitted at least one covered document by the CDRD, CMS has notified the bidder within 90 days after the CDRD if they were missing a covered document by the close of the bid window or if a covered document was missing by the CDRD. We are proposing that when a bidder has submitted at least one covered document by the CDRD, CMS will notify the bidder within 90 days after the CDRD if they have any missing covered document(s) by the close of the bid window. The supplier would have 10 days after such notification to provide the missing covered document(s).

i. Bid Surety Bond Review Process

CMS applied a bid surety bond rider process during bid evaluation for the DMEPOS CBP round in 2021, and we are now proposing to codify this process in regulation for all future rounds. Additionally, we are proposing to correct a technical error in 42 CFR 414.412(g) that happened as a result of a paragraph redesignation in 83 FR 57072.

j. Tribal Exemption From Participating in the DMEPOS CBP

We are proposing to add an exception to the DMEPOS CBP that would allow Medicare payment to Indian Health Service (IHS) and tribally operated facilities and suppliers as noncontract suppliers to furnish competitively bid items and services to American Indian/Alaska Native (AI/AN) Medicare beneficiaries who reside in a CBA during a round of the DMEPOS CBP.

k. Addition of a Termination Clause for the DMEPOS CBP Supplier Contracts

We are proposing in § 414.422 to have the option to unilaterally terminate or modify each applicable DMEPOS CBP supplier contract to allow any Medicare enrolled DMEPOS supplier to furnish the applicable items and services to Medicare beneficiaries if CMS determines that due to a PHE, contract suppliers are unable to furnish certain items and services to beneficiaries in certain areas impacted by a PHE (PHE-impacted area) as required under their respective DMEPOS CBP supplier contracts.

CMS is proposing in § 414.422 to have the option to remove items and services furnished in a PHE-impacted areas from the DMEPOS CBP when all of the following qualifying criteria are met: (1) the Secretary declares a PHE; (2) CMS

determines that verifiable evidence exists of a DMEPOS access problem for beneficiaries for a certain competition or defined area(s) within the competition's CBA; (3) CMS determines that awarding additional DMEPOS CBP supplier contracts, per § 414.414(i), would not address the access concerns; and (4) CMS determines terminating or modifying each impacted DMEPOS CBP supplier contract to exclude certain competition(s) or defined area(s) within the competition's CBA from the DMEPOS CBP would alleviate access concerns.

After termination and/or modification of all applicable DMEPOS CBP supplier contracts, CMS is proposing in § 414.422 to revert back to the general fee-for-service program requirements set forth in 42 CFR part 414 Subpart D for the applicable competition(s) or defined area(s) within a CBA.

l. Technical Change to § 414.408(h)(8)

We are proposing to make a technical change to § 414.408(h)(8) so that it correctly refers to paragraph (h)(8)(ii) instead of paragraph (h)(7)(ii).

m. Adding Definitions of Adjusted Fee Schedule Amount, Competition, and Unadjusted Fee Schedule Amount to § 414.402

The purpose of this proposal is to add definitions of "Adjusted fee schedule amount," "Competition," and "Unadjusted fee schedule amount" to § 414.402 for the purpose of simplifying the regulation text for subpart F.

C. Summary of the Regulatory Impact Analysis

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TABLE 1: SUMMARY OF ECONOMIC COSTS AND TRANSFERS, BY PROPOSED PROVISION

Provision Description	Costs and Cost Savings	Transfers	Other Notes
CY 2026 HH PPS Payment Rate Update		The overall economic impact related to the changes in payments under the HH PPS for CY 2026 is estimated to be -\$1.135 billion (-6.4 percent). The \$1.135 billion decrease in estimated payments for CY 2026 reflects the effects of the CY 2026 proposed home health payment update percentage of 2.4 percent (\$425 million increase), an estimated 3.7 percent decrease* that reflects the effects of the permanent adjustment (\$655 million decrease), an estimated 4.6 percent decrease* that reflects the effects of the temporary adjustment (\$815 million decrease) and an estimated 0.5 percent decrease that reflects the effects of an updated FDL (\$90 million decrease). *The estimated 3.7 percent decrease and the estimated 4.6 percent decrease related to the proposed permanent and temporary adjustments includes all payments, while the proposed -4.059 percent and -5.0 percent adjustments are only applied to the national, standardized 30-Day period payments and does not impact payments for 30-day periods which are LUPAs.	To ensure that home health payments are consistent with statutory payment authority for CY 2026.
HH QRP	The total economic impact of these proposals including the removal of one Living Situation item, two Food items, and one Utilities item as well as the proposal to remove the patient COVID-19 vaccination item, which is proposed for implementation in CY 2026 will result in a reduction of \$17.810,282.		Remove anticipated burden related to the implementation of these items in the OASIS assessment tool.
Expanded HHV/BP Model		The overall economic impact of the expanded HHV/BP Model for CY s 2024 through 2027 is an estimated \$3.376 billion in total savings to FFS Medicare from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to IIHAs competing in the expanded Model. No costs expected.	
HH CoP Technical Updates			Alignment with all-payer requirements provides clarification to HHAs regarding which patients they must collect and submit OASIS information on.

Provision Description	Costs and Cost Savings	Transfers	Other Notes
Medicare and Medicaid Provider Enrollment		We anticipate average annual transfers from providers and suppliers to the Federal Government of approximately \$2.2 billion.	To help ensure that payments are made only to qualified providers and suppliers, which we believe would assist in protecting the Trust Funds and Medicare beneficiaries.
DMEPOS Supplier Accreditation	We estimate a combined average annual cost burden to DMEPOS suppliers and DMEPOS AOs of approximately \$128.3 million.	We anticipate the following average annual transfers: + \$165.8 million in transfers from DMEPOS suppliers to DMEPOS AOs in the form of accreditation fees the suppliers pay to the AOs. + \$3.8 million in transfers from DMEPOS AOs to DMEPOS suppliers in the form of refunds if the AO's approval as a DMEPOS AO is terminated or suspended. + \$664 million in transfers from DMEPOS suppliers to the Federal government based on DMEPOS supplier revocations.	To help better ensure that: (1) DMEPOS AOs are fully qualified to conduct DMEPOS accreditation activities; and (2) all DMEPOS suppliers meet the DMEPOS quality standards.
DMEPOS Prior Authorization	The overall economic impact of the DMEPOS Prior Authorization Exemption provisions is an estimated \$2,497,392 in total savings as a result of reduced workload to the DMEPOS Medicare Administrative Contractors (\$2,243,074) and reduced supplier burden by compliant suppliers not submitting requests for prior authorization (\$254,318).		To reduce supplier burden by not requiring compliant DMEPOS suppliers to submit requests for prior authorization.
DMEPOS Competitive Bidding Program		No economic impact of this regulatory action, thus no associated transfers.	To support the ongoing cost savings and guaranteed beneficiary access offered by the previously implemented DMEPOS CBP. Also, to improve flexibility in providing beneficiaries with the most appropriate medical devices by modifying the payment category of continuous glucose monitors and insulin infusion pumps.

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II. Home Health Prospective Payment System

A. Overview of the Home Health Prospective Payment System

1. Statutory Background

Section 1895(b)(1) of the Act requires the Secretary to establish a Home Health Prospective Payment System (HH PPS) for all costs of home health services paid under Medicare. Section 1895(b)(2)(A) of the Act requires that, in defining a prospective payment amount, the Secretary shall consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services. In accordance with the statute, as amended by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), we issued a final rule which appeared in the July 3, 2000, **Federal Register** (65 FR 41128) to implement the HH PPS legislation.

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring home health agencies (HHAs) to submit data for purposes of measuring health care quality, and linking the quality data submission to the annual applicable home health payment update percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. Pursuant to section 1895(b)(3)(B)(v)(I) of the Act, if an HHA does not submit quality data, the home health market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006, **Federal Register** (71 FR 65935), we issued a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

Section 51001(a)(1)(B) of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) amended section 1895(b) of the Act to require a change to the home health unit of payment to 30-day periods beginning January 1, 2020. Section 51001(a)(2)(A) of the BBA of 2018 added a new subclause (iv) under section 1895(b)(3)(A) of the Act, requiring the Secretary to calculate a standard prospective payment amount (or amounts) for 30-day units of service furnished that end during the 12-month period beginning January 1, 2020, in a

budget neutral manner, such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of service. Section 1895(b)(3)(A)(iv) of the Act requires that the calculation of the standard prospective payment amount (or amounts) for CY 2020 be made before the application of the annual update to the standard prospective payment amount as required by section 1895(b)(3)(B) of the Act.

Additionally, section 1895(b)(3)(A)(iv) of the Act requires that in calculating the standard prospective payment amount (or amounts), the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of service under section 1895(b)(2)(B) of the Act and case-mix adjustment factors established under section 1895(b)(4)(B) of the Act. Section 1895(b)(3)(A)(iv) of the Act further requires the Secretary to provide a description of the behavior assumptions made in notice and comment rulemaking. CMS finalized these behavior assumptions in the CY 2019 HH PPS final rule with comment period (83 FR 56461).

Section 51001(a)(2)(B) of the BBA of 2018 also added a new subparagraph (D) to section 1895(b)(3) of the Act. Section 1895(b)(3)(D)(i) of the Act requires the Secretary annually to determine the impact of differences between assumed behavior changes, as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, section 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as

determined under section 1895(b)(3)(D)(i) of the Act. Such a temporary increase or decrease shall apply only with respect to the year for which such temporary increase or decrease is made, and the Secretary shall not take into account such a temporary increase or decrease in computing the payment amount for a unit of home health services for a subsequent year. Finally, section 51001(a)(3) of the BBA of 2018 amends section 1895(b)(4)(B) of the Act by adding a new clause (ii) to require the Secretary to eliminate the use of therapy thresholds in the case-mix system for CY 2020 and subsequent years.

Division FF, section 4136 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328) amended section 1834(s)(3)(A) of the Act to require that, beginning with 2024, the separate payment for furnishing negative pressure wound therapy (NPWT) be for just the device and not for nursing and therapy services. Payment for nursing and therapy services are to be included as part of payments under the HH PPS. The separate payment for 2024 was required to be equal to the supply price used to determine the relative value for the service under the Medicare Physician Fee Schedule (as of January 1, 2022) for the applicable disposable device updated by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI–U). The separate payment for 2025 and each subsequent year is to be the payment amount for the previous year updated by the percentage increase in the CPI–U (United States city average) for the 12-month period ending in June of the previous year reduced by the productivity adjustment as described in section 1886(b)(3)(B)(xi)(II) of the Act for such year. The CAA, 2023 also added section 1834(s)(4) of the Act to require that beginning with 2024, as part of submitting claims for the separate payment, the Secretary shall accept, and process claims submitted using the type of bill that is most commonly used by home health agencies to bill services under a home health plan of care.

2. Current System for Payment of Home Health Services

For home health periods of care beginning on or after January 1, 2020, Medicare makes payment under the HH PPS on the basis of a national, standardized 30-day period payment rate that is adjusted for case-mix and area wage differences in accordance with section 51001(a)(1)(B) of the BBA of 2018. The national, standardized 30-day period payment rate includes

payment for the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is also part of the national, standardized 30-day period rate. Durable medical equipment (DME) provided as a home health service, as defined in section 1861(m)(5) of the Act, is paid the fee schedule amount or is paid through the competitive bidding program and such payment is not included in the national, standardized 30-day period payment amount. Additionally, the 30-day period payment rate does not include payment for certain injectable osteoporosis drugs and disposable negative pressure wound therapy (dNPWT) devices, but such drugs and devices must be billed by the HHA while a patient is under a home health plan of care, as the law requires separate consolidated billing of certain osteoporosis drugs and dNPWT devices.

To better align payment with patient care needs and to better ensure that clinically complex and ill beneficiaries have adequate access to home health care, in the CY 2019 HH PPS final rule with comment period (83 FR 56406), we finalized case-mix methodology refinements, including the removal of

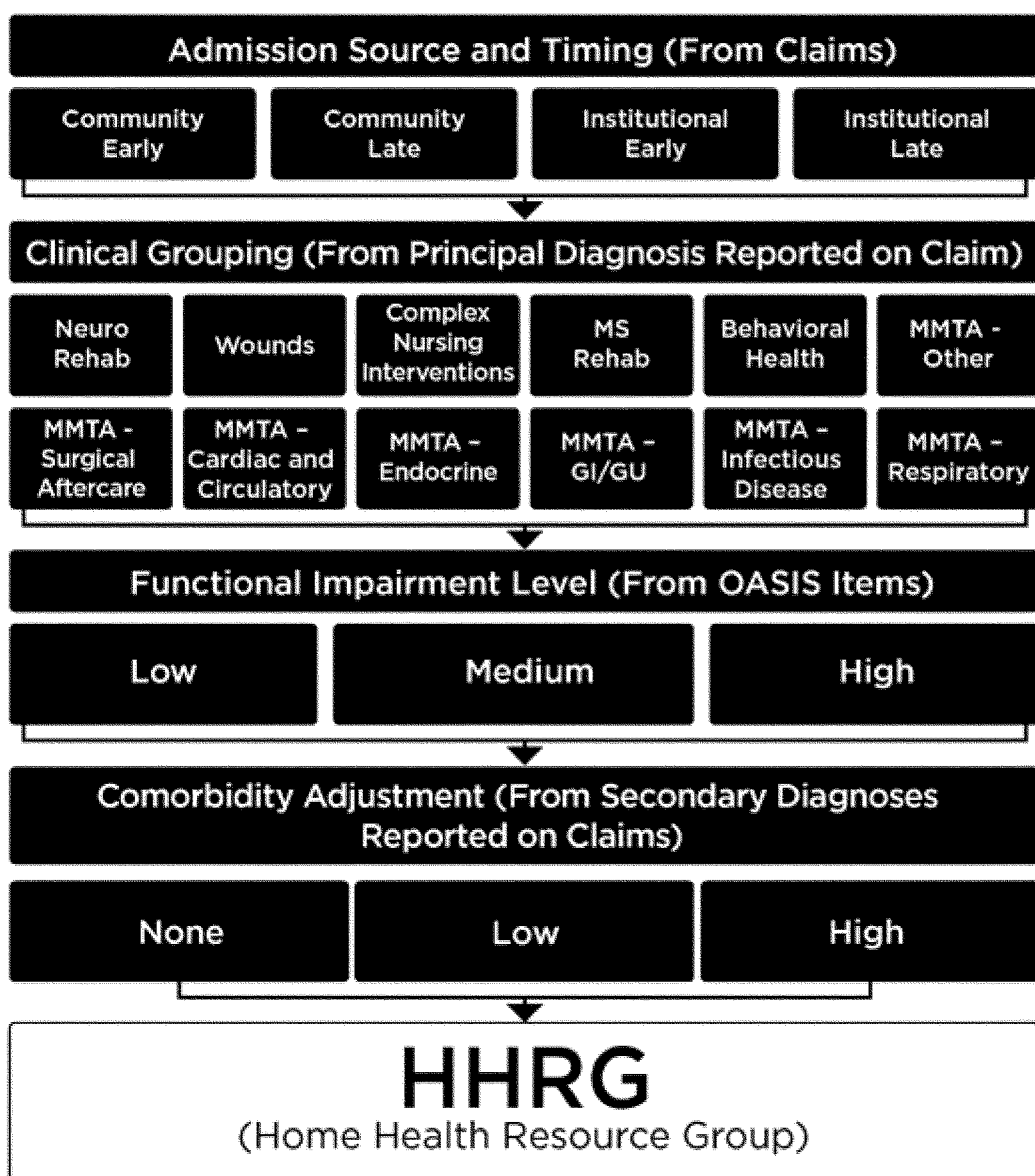
therapy thresholds, through the Patient-Driven Groupings Model (PDGM) for home health periods of care beginning on or after January 1, 2020. The PDGM did not change eligibility or coverage criteria for Medicare home health services, and as long as the individual meets the criteria for home health services as described at 42 CFR 409.42, the individual can receive Medicare home health services, including therapy services. For more information about the role of therapy services under the PDGM, we refer readers to the Medicare Learning Network (MLN) Matters article SE20005 available at <https://www.cms.gov/regulations-and-guidance/guidancetransmittals2020-transmittals/se20005>. To adjust for case-mix for 30-day periods of care beginning on and after January 1, 2020, the HH PPS uses a 432-category case-mix classification system to assign patients to a home health resource group (HHRG) using patient characteristics and other clinical information from Medicare claims and the Outcome and Assessment Information Set (OASIS) instrument. These 432 HHRGs represent the different payment groups based on five main case-mix categories under the PDGM, as shown in figure 1. Each HHRG has an associated case-mix

weight that is used in calculating the payment for a 30-day period of care. For periods of care with visits less than the low-utilization payment adjustment (LUPA) threshold for the HHRG, Medicare pays national per-visit rates based on the discipline(s) providing the services. Medicare also adjusts the national standardized 30-day period payment rate for certain intervening events that are subject to a partial payment adjustment. For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

Under this case-mix methodology, case-mix weights are generated for each of the different PDGM payment groups by regressing resource use for each of the five categories (admission source, timing, clinical grouping, functional impairment level, and comorbidity adjustment) using a fixed effects model. A detailed description of each of the case-mix variables under the PDGM have been described previously, and we refer readers to the CY 2021 HH PPS final rule (85 FR 70303 through 70305) for further information.

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Figure 1: Case-Mix Variables in the PDGM



Notes: MMTA (Medication Management, Teaching and Assessment), MS (Musculoskeletal), GI (Gastrointestinal tract), GU (Genitourinary system)

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B. Monitoring the Effects of the Implementation of the PDGM

1. Routine PDGM Monitoring

CMS routinely analyzes Medicare home health benefit utilization, including but not limited to, overall total 30-day periods of care and average periods of care per HHA user; distribution of the type of visits in a 30-day period of care; the percentage of periods that receive the LUPA; estimated costs; the percentage of 30-day periods of care by clinical group, comorbidity adjustment, admission source, timing, and functional impairment level; the proportion of 30-

day periods of care with and without any therapy visits, nursing visits, and/or aide/social worker visits, and monitoring of home health visits using telecommunications technology and remote patient monitoring. For the monitoring included in this rule, we examine simulated data for CYs 2018 and 2019 and actual data for CYs 2020, 2021, 2022, 2023, and 2024 for 30-day periods of care. We refer readers to the CY 2022 HH PPS final rule (*86 FR 35881*) for discussion about simulated data for CYs 2018 and 2019.

(a) Utilization

Table 2 shows the overall utilization of home health services. This data indicates the average number of 30-day

periods of care per unique HHA beneficiary is higher in CY 2024 compared to CYs 2021, 2022, and 2023. The data also indicates that the number of 30-day periods of care decreased between CY 2018 and CY 2024. Table 3 shows the average utilization of visits per 30-day period of care by home health discipline. Table 4 shows the proportion of 30-day periods of care that are LUPAs and the average number of visits per discipline of those LUPA 30-day periods of care over time. The data show a decreasing trend in the average number of visits per 30-day period and average number of visits per discipline for LUPA 30-day periods of care between CY 2018 and CY 2024.

TABLE 2: OVERALL UTILIZATION OF HOME HEALTH SERVICES, CYs 2018-2024

Volume of Periods and Number of Beneficiaries	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
30-Day Periods of Care	9,336,898	8,744,171	8,423,688	9,269,971	8,593,266	8,319,064	8,118,120
Unique Beneficiaries	2,980,385	2,802,560	2,850,916	3,017,464	2,831,138	2,715,010	2,620,520
Average Number of 30-Day Periods per Unique Beneficiary	3.13	3.12	2.95	3.07	3.04	3.06	3.10

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health Limited Data Set (LDS). CY 2020 data was accessed from the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) on July 12, 2021. CY 2021 data was accessed from the CCW VRDC on July 14, 2022. CY 2022 data was accessed from the CCW VRDC on July 13, 2023. CY 2023 data was accessed from the CCW VRDC on July 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, partial episode payments (PEPs), and outliers).

TABLE 3: UTILIZATION OF VISITS PER 30-DAY PERIODS OF CARE BY HOME HEALTH DISCIPLINE, CYs 2018-2024

Discipline	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Skilled Nursing	4.53	4.49	4.35	4.05	3.90	3.87	3.84
Physical Therapy	3.30	3.33	2.70	2.74	2.77	2.77	2.73
Occupational Therapy	1.02	1.07	0.79	0.78	0.77	0.76	0.73
Speech Therapy	0.21	0.21	0.16	0.15	0.14	0.14	0.13
Home Health Aide	0.72	0.67	0.54	0.48	0.43	0.42	0.39
Social Worker	0.08	0.08	0.06	0.05	0.05	0.05	0.04
Total (all disciplines)	9.86	9.85	8.59	8.25	8.06	8.00	7.86

Source: CY 2018 and CY 2019 simulated PDGM data with behavior assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

TABLE 4: THE PROPORTION OF 30-DAY PERIODS OF CARE THAT ARE LUPAs AND THE AVERAGE NUMBER OF VISITS BY HOME HEALTH DISCIPLINE FOR LUPA HOME HEALTH PERIODS, CYs 2018-2024

	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Total LUPA % of Overall 30-day Periods	6.7%	6.8%	8.7%	7.9%	7.8%	6.9%	6.9%
Discipline (Average # visits for LUPA home health periods)							
Skilled Nursing	1.15	1.14	1.19	1.12	1.08	0.99	0.99
Physical Therapy	0.43	0.46	0.53	0.55	0.60	0.51	0.52
Occupational Therapy	0.07	0.07	0.08	0.08	0.09	0.07	0.08
Speech Therapy	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Home Health Aide	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Social Worker	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Total	1.69	1.71	1.84	1.79	1.81	1.61	1.63

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

(b) Analysis of 2023 Cost Report Data for 30-Day Periods of Care

In the CY 2025 HH PPS proposed rule (89 FR 55320), we provided a summary of analysis on FY 2022 HHA cost report data, as this was the most recent and complete cost report data at the time of rulemaking, and CY 2023 claims to estimate 30-day period of care costs. Our analysis showed that the CY 2023 national, standardized 30-day period payment rate of \$2,010.69 was

approximately 32 percent more than the estimated CY 2023 estimated 30-day period cost of \$1,527.23.

Using this same process in this proposed rule to compare home health payment to costs, we examined 2023 HHA Medicare cost reports (CMS Form 1728–20, OMB No. 0938–0222), as this is the most recent and complete cost report data at the time of rulemaking. We also examined CY 2024 home health claims to estimate 30-day period of care

costs. We excluded LUPAs and partial payment adjustments when calculating the average number of visits. The 2023 average NRS costs per visit is \$4.58. To update the estimated 30-day period of care costs, we begin with the 2023 average costs per visit with NRS for each discipline and multiply that amount by the CY 2024 home health payment update percentage of 3.0 percent (or a home health payment update factor of 1.03). That amount for

each discipline is then multiplied by the 2024 average number of visits by discipline to determine the 2024

estimated 30-day period costs. Table 5 shows the estimated average costs for 30-day periods of care by discipline

with NRS and the total 30-day period of care costs with NRS for CY 2024.

TABLE 5: ESTIMATED AVERAGE COSTS FOR 30-DAY PERIODS OF CARE IN CY 2024

Discipline	2023 Average Cost per Visit	2024 Average Number of Visits	2024 Market Basket Update Factor	2024 Estimated 30-Day Period Costs
Skilled Nursing	\$184.60	4.05	1.03	\$770.06
Physical Therapy	\$181.18	2.90	1.03	\$541.18
Occupational Therapy	\$178.97	0.78	1.03	\$143.78
Speech Pathology	\$206.56	0.14	1.03	\$29.79
Medical Social Services	\$318.84	0.05	1.03	\$16.42
Home Health Aides	\$109.00	0.42	1.03	\$47.15
Total		8.34		\$1,548.39

Source: 2023 Medicare cost report data obtained during January 2025. Home health visit information came from 30-day periods with a through date in CY2024 (Obtained from the CCW VRDC on March 13, 2025).

Note: The average number of visits in 2024 excludes LUPAs and PEPs.

The CY 2024 national standardized 30-day period payment rate was \$2,057.35, which is approximately 33 percent more than the CY 2024 estimated 30-day period cost of \$1,548.39. Moreover, as shown in table3

in this proposed rule, HHAs have reduced visits under PDGM in CY 2024.

(c) Clinical Groupings and Comorbidities

Each 30-day period of care is grouped into one of 12 clinical groups, which describes the primary reason for which

a patient is receiving home health services under the Medicare home health benefit. The clinical grouping is based on the principal diagnosis reported on the home health claim. Table 6 shows the distribution of the 12 clinical groups over time.

TABLE 6: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY THE 12 PDGM CLINICAL GROUPS, CYs 2018-2024

Clinical Grouping	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Behavioral Health	1.7%	1.5%	2.3%	2.4%	2.3%	2.2%	2.1%
Complex	2.6%	2.5%	3.5%	3.3%	3.2%	3.1%	3.1%
MMTA – Cardiac	16.5%	16.1%	18.9%	18.5%	17.9%	17.5%	17.1%
MMTA – Endocrine	17.3%	17.4%	7.2%	6.9%	6.8%	7.0%	7.1%
MMTA – GI/GU	2.2%	2.3%	4.7%	4.7%	4.9%	5.0%	5.2%
MMTA – Infectious	2.9%	2.7%	4.8%	4.6%	4.6%	4.7%	4.8%
MMTA – Other	4.7%	4.7%	3.1%	3.6%	3.5%	3.7%	3.8%
MMTA – Respiratory	4.3%	4.1%	7.8%	8.0%	7.8%	7.2%	7.0%
MMTA – Surgical Aftercare	1.8%	1.8%	3.6%	3.4%	3.4%	3.5%	3.5%
MS Rehab	17.1%	17.3%	19.4%	19.8%	20.8%	21.2%	21.4%
Neuro	14.4%	14.5%	10.5%	10.9%	11.0%	10.9%	10.8%
Wound	14.5%	15.1%	14.2%	13.9%	13.7%	14.0%	14.0%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

Thirty-day periods of care receive a comorbidity adjustment category based on certain secondary diagnoses reported on home health claims. These diagnoses are based on a home health specific list of clinically and statistically significant

secondary diagnosis subgroups with similar resource use. We refer readers to section II.D. of this proposed rule and the CY 2020 HH PPS final rule with comment period (84 FR 60493) for further information on the comorbidity

adjustment categories. Home health 30-day periods of care can receive a low or a high comorbidity adjustment, or no comorbidity adjustment. Table 7 shows the distribution of 30-day periods of

Care by comorbidity adjustment category for all 30-day periods.

TABLE 7: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY COMORBIDITY ADJUSTMENT CATEGORY FOR 30-DAY PERIODS, CY 2018-2024

Comorbidity Adjustment	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
None	55.6%	52.0%	49.1%	49.6%	37.3%	30.7%	29.1%
Low	35.3%	38.0%	36.9%	36.8%	47.8%	52.6%	55.4%
High	9.2%	10.0%	14.0%	13.5%	14.9%	16.7%	15.4%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

(d) Admission Source and Timing

Each 30-day period of care is classified into one of two admission source categories—community or institutional, depending on what healthcare setting was utilized in the 14 days prior to receiving home health care. Thirty-day periods of care for beneficiaries with any inpatient acute care hospitalizations, inpatient psychiatric facility (IPF) stays, skilled nursing facility (SNF) stays, inpatient rehabilitation facility (IRF) stays, or long-term care hospital (LTCH) stays within 14-days prior to a home health

admission are designated as institutional admissions. The institutional admission source category also includes patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted. All other 30-day periods of care would be designated as community admissions.

Thirty-day periods of care are classified as “early” or “late” depending on when they occur within a sequence of 30-day periods of care. The first 30-

day period of care is classified as early and all subsequent 30-day periods of care in the sequence (second or later) are classified as late. A subsequent 30-day period of care would not be considered early unless there is a gap of more than 60 days between the end of one previous period of care and the start of another. Information regarding the timing of a 30-day period of care comes from Medicare home health claims data and not the OASIS assessment to determine if a 30-day period of care is “early” or “late”. Table 8 shows the distribution of 30-day periods of care by admission source and period timing.

TABLE 8: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY ADMISSION SOURCE AND PERIOD TIMING, CYs 2018-2024

Admission Source	Period Timing	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Community	Early	13.5%	13.8%	12.4%	11.6%	11.7%	11.6%	11.5%
Community	Late	61.1%	60.9%	61.8%	63.7%	63.1%	63.1%	63.6%
Institutional	Early	18.6%	18.4%	20.0%	18.6%	19.2%	19.3%	18.8%
Institutional	Late	6.8%	6.9%	5.8%	6.1%	6.0%	6.1%	6.1%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

(e) Functional Impairment Level

Each 30-day period of care is placed into one of three functional impairment levels (low, medium, or high) based on responses to certain OASIS functional items associated with grooming, bathing, dressing, ambulating, transferring, and risk for hospitalization. The specific OASIS items that are used for the functional impairment level are found in table 7 in the CY 2020 HH PPS final rule with comment period (84 FR 60490). Responses to these OASIS items

are grouped together into response categories with similar resource use and each response category has associated points. A more detailed description as to how these response categories were established can be found in the technical report, “Overview of the Home Health Groupings Model” posted on the HHA web page.¹ The sum of these points results in a functional

¹ <https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health/home-health-patient-driven-groupings-model>.

impairment score used to group 30-day periods of care into a functional impairment level with similar resource use. The scores associated with the functional impairment levels vary by clinical group to account for differences in resource utilization. A patient’s functional impairment level remains the same for the first and second 30-day periods of care unless there is a significant change in condition that warrants an “other follow-up” assessment prior to the second 30-day

period of care. For each 30-day period of care, the Medicare claims processing system looks for occurrence code 50 on

the claim to correspond to the M0090 date of the applicable assessment. Table

9 shows the distribution of 30-day periods by functional impairment level.

TABLE 9: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY FUNCTIONAL IMPAIRMENT LEVEL. CYs 2018-2024

Functional Impairment Level	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Low	33.9%	31.9%	25.7%	23.3%	28.1%	29.8%	30.3%
Medium	34.9%	35.5%	32.7%	32.6%	33.1%	31.8%	31.8%
High	31.2%	32.6%	41.7%	44.2%	38.8%	38.4%	37.8%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

(f) Therapy and Non-Therapy Visits

Beginning in CY 2020, section 1895(b)(4)(B)(ii) of the Act eliminated the use of therapy thresholds in calculating payments for CY 2020 and subsequent years. Prior to implementation of the PDGM, HHAs could receive an adjustment to payment based on the number of therapy visits provided during a 60-day episode of care. We examined the proportion of actual 30-day periods of care with and without therapy visits. To be covered as skilled therapy, the services must require the skills of a qualified therapist

(that is, PT, OT, or SLP) or qualified therapist assistant and must be reasonable and necessary for the treatment of the patient's illness or injury. As shown in table 3, we monitor the number of visits per 30-day period of care by each home health discipline. Any 30-day period of care can include both therapy and non-therapy visits. If any 30-day period of care consisted of only visits for PT, OT, or SLP, then this 30-day period of care is considered "therapy only". If any 30-day period of care consisted of only visits for skilled nursing, home health aide, or social

worker, then this 30-day period of care is considered "no therapy". If any 30-day period of care consisted of at least one therapy visit and one non-therapy, then this 30-day period of care is considered "therapy + non-therapy". Table 10 shows the proportion of 30-day periods of care with only therapy visits, at least one therapy visit and one non-therapy visit, and no therapy visits. Figure 2 shows the proportion of 30-day periods of care by the number of therapy visits (excluding zero) provided during 30-day periods of care.

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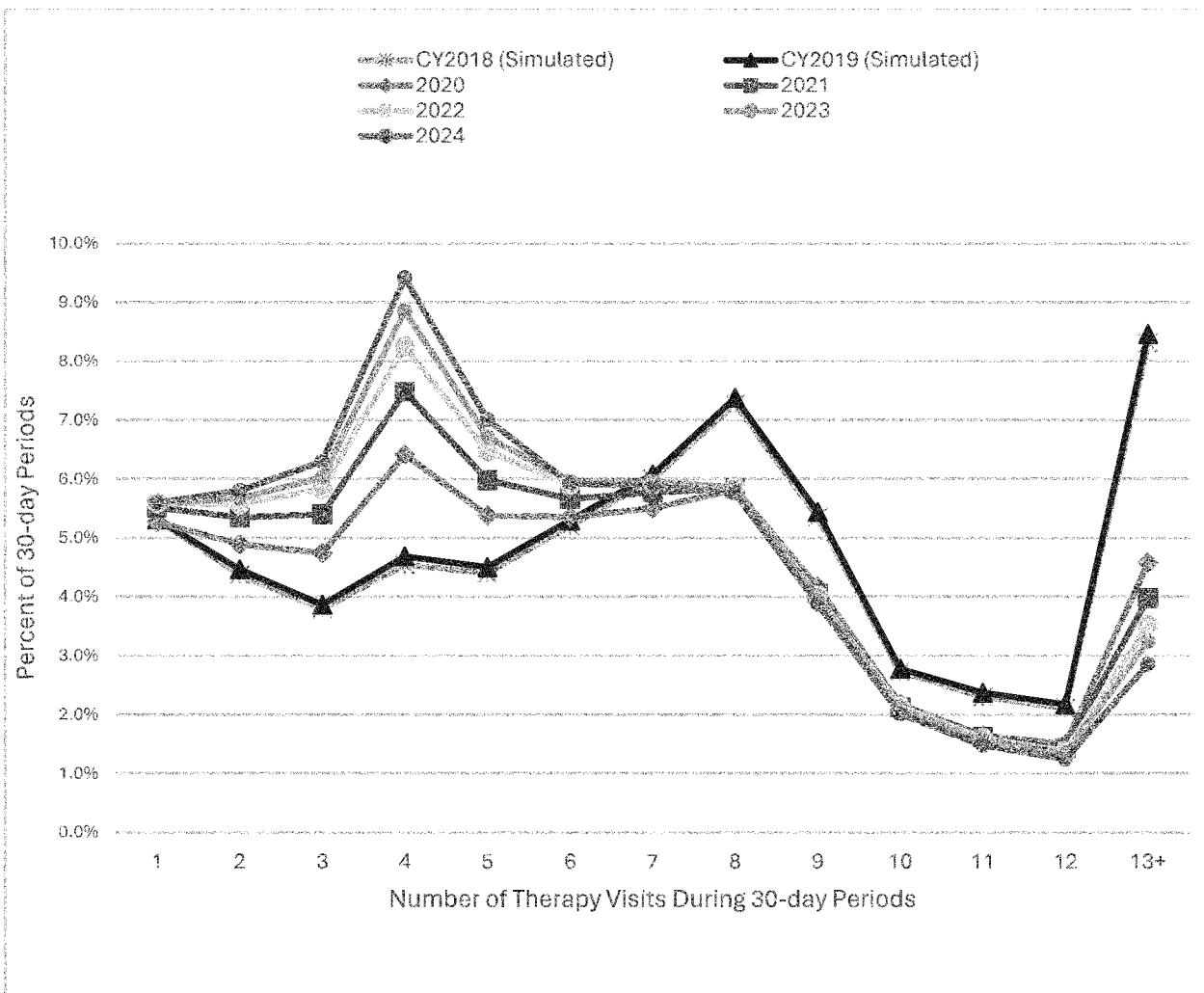
TABLE 10: PROPORTION OF 30-DAY PERIODS OF CARE WITH ONLY THERAPY, AT LEAST ONE THERAPY VISIT + NON-THERAPY VISIT, AND NO THERAPY VISITS FOR CYs 2018-2024

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Therapy Only	13.5%	14.4%	15.2%	17.7%	19.3%	20.0%	20.4%
Therapy + Non-Therapy	48.2%	48.4%	42.2%	42.5%	42.7%	42.8%	42.7%
No Therapy	38.3%	37.2%	42.6%	39.8%	38.0%	37.2%	36.9%
Total 30-day periods	9,336,898	8,744,171	8,423,688	9,269,971	8,593,266	8,319,064	8,118,120

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

FIGURE 2: PROPORTION OF 30-DAY PERIODS OF CARE BY THE NUMBER OF THERAPY VISITS DURING 30-DAY PERIODS, CYs 2018-2024



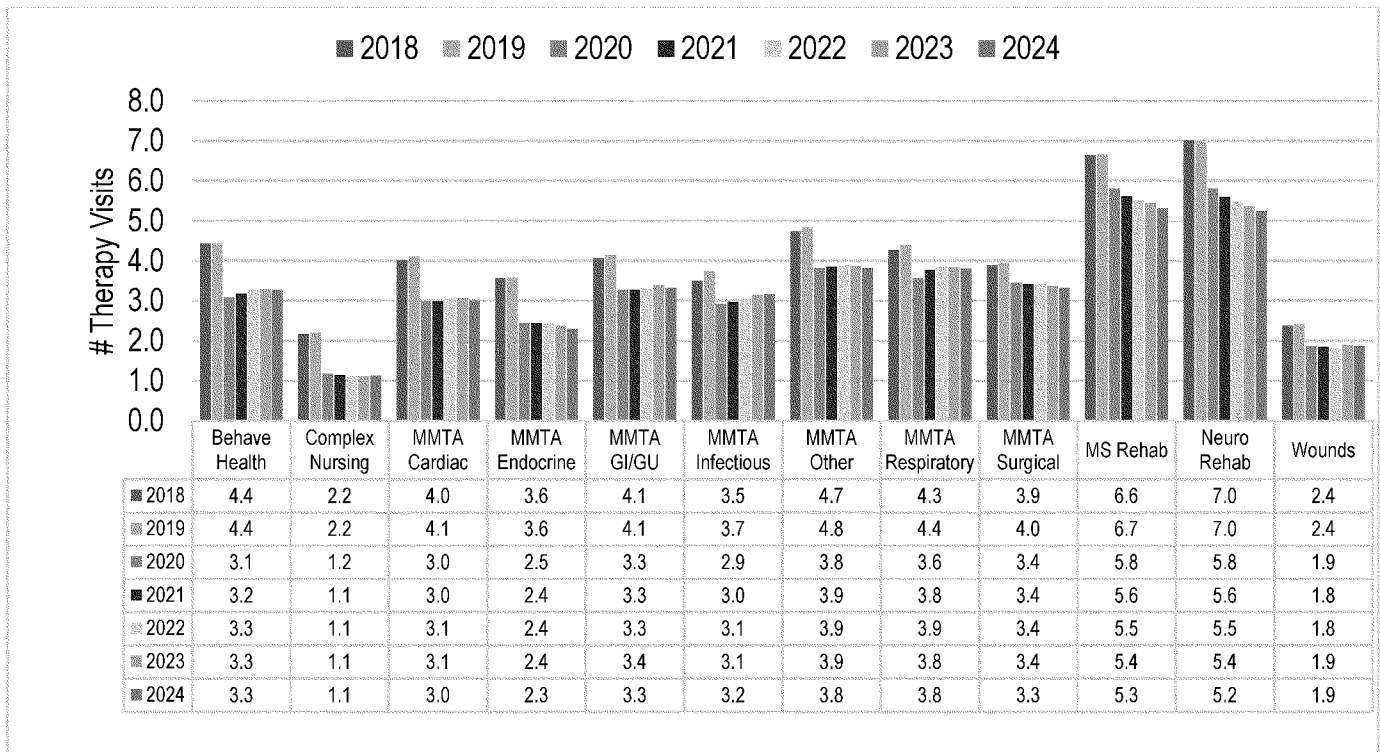
Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on July 13, 2023. CY 2023 PDGM data was accessed from the CCW VRDC on July 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

Figures 2 and 3 indicate there have been changes in the distribution of both therapy and non-therapy visits in CY 2024 compared to CY 2023. For example, the proportion of 30-day

periods with one through five therapy visits during a 30-day period increased in CY 2024 compared to prior years. Comparing therapy utilization from before the PDGM (CYs 2018 and 2019)

to after the implementation of the PDGM (CYs 2020–2024), we also see an overall decline in therapy visits across all clinical groups, as shown in Figure 3.

FIGURE 3: AVERAGE THERAPY VISITS PER 30-DAY PERIOD BY CLINICAL GROUP, CYs 2018-2024

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on July 13, 2023. CY 2023 PDGM data was accessed from the CCW VRDC on July 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

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We also examined the proportion of 30-day periods of care with and without skilled nursing, social work, or home health aide visits. Table 11 shows the

number of 30-day periods of care with only skilled nursing visits, at least one skilled nursing visit and one other visit type (therapy or non-therapy), and no

skilled nursing visits. Table 12 shows the number of 30-day periods of care with and without home health aide or social worker visits.

TABLE 11: PROPORTION OF 30-DAY PERIODS OF CARE WITH ONLY SKILLED NURSING, SKILLED NURSING + OTHER VISIT TYPE, AND NO SKILLED NURSING VISITS FOR CYs 2018-2024

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Skilled Nursing Only	33.8%	33.1%	38.5%	36.2%	34.7%	34.1%	33.9%
Skilled Nursing + Other	51.6%	51.5%	45.3%	45.0%	45.0%	44.8%	44.6%
No Skilled Nursing	14.7%	15.5%	16.2%	18.8%	20.4%	21.1%	21.5%
Total 30-day periods	9,336,898	8,744,171	8,423,688	9,269,971	8,593,266	8,319,064	8,118,120

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on July 13, 2023. CY 2023 PDGM data was accessed from the CCW VRDC on July 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

TABLE 12: PROPORTION OF 30-DAY PERIODS OF CARE WITH AND WITHOUT HOME HEALTH AIDE AND/OR SOCIAL WORKER VISITS FOR CYs 2018-2024

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Any HH aide and/or social worker	16.6%	15.9%	13.2%	12.2%	11.3%	10.9%	10.3%
No HH aide and/or social worker	83.4%	84.1%	86.8%	87.8%	88.7%	89.1%	89.7%
Total 30-day periods	9,336,898	8,744,171	8,423,688	9,269,971	8,593,266	8,319,064	8,118,120

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on July 13, 2023. CY 2023 PDGM data was accessed from the CCW VRDC on July 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

(g) Home Health Services Using Telecommunications Technology

As discussed in the CY 2023 final rule (87 FR 66858), we began collecting data on the use of telecommunications technology used during a home health period using three G-codes reported on home health claims. Collecting data on services furnished via telecommunications technology on claims allows CMS to analyze the characteristics of patients using services provided remotely. The monitoring discussion illustrates which services are most frequently furnished via telecommunication technology and generally how long remote patient monitoring is utilized.

We began collecting this information from HHAs on a voluntary basis on January 1, 2023, and have required this information to be reported on claims starting on July 1, 2023 (87 FR 66858). The three G-codes help identify when home health services are furnished using synchronous telemedicine rendered via a real-time two-way audio and video telecommunications system (G0320); synchronous telemedicine rendered via telephone or other real-time interactive audio-only telecommunications systems (G0321); and the collection of physiologic data digitally stored and/or transmitted by the patient to the home health agency, that is, remote patient monitoring

(G0322). We capture the usage and length of remote patient monitoring using the start date of the remote patient monitoring and the number of days of monitoring indicated on the claim. We also looked at the disciplines most often providing remote patient monitoring. We examined the utilization of telecommunications technology devices during a home health period and remote patient monitoring by looking at home health claims that included the three G-codes. Tables 13 and 14 shows that the use of telecommunications services reported on CY 2024 home health claims are low (roughly 2 percent of all CY 2024 claims) and are mainly associated with skilled nursing.

TABLE 13: TELEHEALTH VISITS RECORDED ON HOME HEALTH CLAIMS (CY 2024)

	Claims with at Least 1 Telehealth Visit	Number of Telehealth Visits	Unique Beneficiaries with at Least 1 Telehealth Visit	Unique Providers with at Least 1 Telehealth Visit
Skilled Nursing	139,730	284,854	96,535	1,087
PT	26,362	43,189	20,950	566
OT	5,422	8,805	4,303	325
SLP	1,470	2,312	1,045	166
Aide	1	1	1	1
MSS	4,675	5,337	4,137	285

Source: CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

TABLE 14: REMOTE PATIENT MONITORING DAYS RECORDED ON HOME HEALTH CLAIMS (CY 2024)

	Claims with at Least 1 Day of Remote Patient Monitoring	Number of Remote Patient Monitoring Days	Unique Beneficiaries with at Least 1 Day of Remote Patient Monitoring	Unique Providers with at Least 1 Day of Remote Patient Monitoring
Skilled Nursing	38,513	679,102	20,786	455
PT	694	11,266	535	108
OT	76	1,253	68	26
SLP	124	2,143	79	14
Aide	29	596	23	13
MSS	176	4,148	117	7

Source: CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

We will continue to monitor the provision of home health services, including any changes in the number and duration of home health visits, composition of the disciplines providing such services, telecommunications technology used during home health periods, and overall home health payments to determine if refinements to the case-mix adjustment methodology or other policies may be needed in the future.

C. Proposed CY 2026 Payment Adjustments Under the HH PPS

1. Proposed Behavior Adjustments Under the HH PPS

a. Background

As discussed in section II.A.1. of this proposed rule, starting in CY 2020, the Secretary was required by section 1895(b)(2)(B) of the Act to change the unit of payment under the HH PPS from a 60-day episode of care to a 30-day period of care. CMS was also required to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and the case-mix adjustment factors that eliminated the use of therapy thresholds. In the CY 2019 HH PPS final rule with comment period (83 FR 56455), we finalized three behavior change assumptions which were also described in the CY 2022 and 2023 HH PPS rules (86 FR 35890, 87 FR 37614, and 87 FR 66795 through 66796). In the CY 2020 HH PPS final rule with comment period (84 FR 60519), we included these behavior change assumptions in the calculation of the 30-day budget neutral payment amount for CY 2020, finalizing a negative 4.36 percent behavior change assumption adjustment (“assumed behaviors”). We did not propose any changes for CYs 2021 and 2022 related to the behavior

change assumptions finalized in the CY 2019 HH PPS final rule with comment period, or to the negative 4.36 percent behavior change assumption adjustment, finalized in the CY 2020 HH PPS final rule with comment period.

In the CY 2023 HH PPS final rule (87 FR 66796), we stated that we had concluded, based on our annual monitoring at that time, that the three expected behavior changes did in fact occur as a result of the implementation of the PDGM and that other behaviors, such as changes in the provision of therapy and changes in functional impairment levels, had also occurred. We also reminded readers that in the CY 2020 HH PPS final rule with comment period (84 FR 60513), we stated we interpret actual behavior changes to encompass behavior changes that were previously outlined as assumed by CMS, and other behavior changes not identified at the time we established the budget-neutral 30-day payment rate for CY 2020. In the CY 2023 HH PPS final rule (87 FR 66796), we provided supporting evidence that indicated the number of therapy visits declined in CYs 2020 and 2021, as well as a slight decline in therapy visits beginning in CY 2019 after the finalization of the removal of therapy thresholds, but prior to implementation of the PDGM. In section II.B.1. of the CY 2025 HH PPS proposed rule (89 FR 55318), our analysis continued to show the actual 30-day periods are similar overall to the simulated 30-day periods as well as a continued decline in therapy visits, indicating that HHAs changed their behavior to reduce therapy visits. Although the analysis demonstrates evidence of individual behavior changes (for example, in the volume of visits for LUPAs, therapy sessions, etc.), we use the entirety of the behaviors in order to calculate estimated aggregate

expenditures. The law instructs us to ensure that estimated aggregate expenditures under the PDGM are equal to the estimated aggregate expenditures that otherwise would have been made under the prior system.

Section 4142(a) of the CAA, 2023 required CMS to present, to the extent practicable, a description of the actual behavior changes occurring under the HH PPS from CYs 2020 through 2026. This subsection of the CAA, 2023 also required CMS to provide datasets underlying the simulated 60-day episodes and discuss and provide time for stakeholders to provide input on and ask questions about the payment rate development for CY 2023. CMS complied with these requirements by posting online both the supplemental limited data set (LDS) and descriptive files and the description of actual behavior changes that affected CY 2023 payment rate development. Additionally, on March 29, 2023, CMS conducted a webinar entitled “Medicare Home Health Prospective Payment System (HH PPS) Calendar Year (CY) 2023 Behavior Change Recap, 60-Day Episode Construction Overview, and Payment Rate Development.” The webinar was open to the public and discussed the actual behavior changes that occurred upon implementation of the PDGM; our approach used to construct simulated 60-day episodes using 30-day periods; payment rate development for CY 2023; and information on the supplemental data files containing information on the simulated 60-day episodes and actual 30-day periods used in calculating the permanent adjustment to the payment rate. Materials from the webinar, including the presentation and the CY 2023 descriptive statistics from the supplemental LDS files containing information on the number of simulated

60-day episodes and actual 30-day periods in CY 2021 that were used to construct the permanent adjustment to the payment rate, as well as information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments, can be found on the Home Health Patient-Driven Groupings Model web page at <https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health/home-health-patient-driven-groupings-model>.

b. Method to Annually Determine the Impact of Differences Between Assumed Behavior Changes and Actual Behavior Changes on Estimated Aggregate Expenditures

In the CY 2023 HH PPS final rule (87 FR 66804), we finalized the methodology to evaluate the impact of the differences between assumed and actual behavior changes on estimated aggregate expenditures. In the CY 2024 HH PPS final rule (88 FR 77687 through 77688), we provided an overview of the methodology with detailed instructions for each step.

Under the prior 153-group system (and the first three years for assessments associated with the PDGM completed prior to CY 2023), HHAs submitted the Outcome and Assessment Information Set (OASIS) instrument version D. However, OMB approved an updated version of the OASIS instrument, OASIS-E under OMB control number 0938-1279,² on November 30, 2022, effective January 1, 2023. Therefore, in the CY 2025 HH PPS final rule (89 FR 88364), we finalized two additional methodological assumptions related to mapping and imputation of OASIS-D responses from OASIS-E. We refer readers to the CY 2024 and CY 2025 HH PPS final rules for further information about the methodology.

c. Calculating Permanent and Temporary Payment Adjustments

To adjust the base payment rate based on increases or decreases in estimated aggregate expenditures that result from differences between assumed behavior changes and actual behavior changes for 2020 through 2026, we calculate one or more permanent prospective adjustments by calculating the percent change between the actual 30-day base payment rate and the recalculated 30-day base payment rate. This percent change is converted into an adjustment factor and applied in the annual rate update process.

To account for increases or decreases in estimated aggregate expenditures that result from differences between assumed behavior changes and actual behavior changes from 2020 through 2026, we calculate one or more temporary prospective adjustments by calculating the dollar amount difference between the estimated aggregate expenditures from all 30-day periods using the recalculated 30-day base payment rate, and the aggregate expenditures for all 30-day periods using the actual 30-day base payment rate for each of those years once data is available (87 FR 66804). In other words, when determining the dollar amount of aggregate expenditures in prior years that we must offset in future years, we use the full dataset of actual 30-day periods using both the actual and recalculated 30-day base payment rates to ensure that the utilization and distribution of claims are the same. In accordance with section 1895(b)(3)(D)(iii) of the Act, each temporary adjustment applies prospectively but, as its name suggests, only with respect to the year for which such temporary increase or decrease is made. Therefore, after we determine the dollar amount we plan to reconcile in a given year, we calculate a temporary adjustment factor to be applied to the base payment rate for that year. The temporary adjustment factor is based on an estimated number of 30-day periods in the next year using historical data trends, and as applicable, controls for any permanent adjustment factor, case-mix weight recalibration neutrality factor, wage index budget neutrality factor, and the home health payment update. The temporary adjustment factor is applied last since the adjustment applies only to the respective year. That is, the temporary adjustment is not permanently fixed into future base payment rates. We refer readers to the CY 2024 HH PPS final rule (88 FR 77689 through 77694) for analysis of CYs 2020 through 2022 claims and the CY 2025 HH PPS final rule (89 FR 88366 through 88369) for analysis of CY 2023 claims. Additionally, at the end of this section we provide a summary table for the permanent adjustment and temporary dollar amounts calculated for each year.

d. CY 2024 Preliminary Claims Results

We will continue the practice of using the most recent complete home health claims data available at the time of rulemaking. While the CY 2024 analysis presented in this proposed rule uses the most complete data available at the time, it is considered preliminary and, as more data become available from the

latter half of CY 2024, we would update our analysis in the final rule. The CY 2026 final rule would use the complete CY 2024 data for determining any permanent and temporary adjustments needed to the CY 2026 payment rate. However, while the claims data and the permanent and temporary adjustments results would be considered complete for CY 2026, any adjustments to future payment rates may be subject to additional considerations such as permanent adjustments taken in previous years.

The claims data used in rulemaking is released twice each year in the HH PPS LDS file, one for the proposed and one for the final. Accordingly, the HH PPS LDS file released with this proposed rule includes two files: the actual CY 2024 30-day periods and the CY 2024 simulated 60-day episodes.

We remind readers a data use agreement (DUA) is required to purchase the CY 2026 proposed HH PPS LDS file using the CMS-R-0235A form under OMB control number 0938-0734. Access would be granted for both the 30-day periods and the simulated 60-day episodes under one DUA. Visit the HH PPS LDS web page for more information.³ In addition, the proposed CY 2026 Home Health Descriptive Statistics from the LDS Files spreadsheet is available on the HH PPS Regulations and Notices web page,⁴ does not require a DUA, and is available at no cost to interested parties. The spreadsheet contains information on the number of simulated 60-day episodes and actual 30-day periods in CY 2024 that were used to determine the adjustments. The spreadsheet also provides information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments.

e. Applying the Methodology to CY 2024 Data To Determine the CY 2026 Permanent and Temporary Adjustments

Using the methodology finalized in the CY 2023 HH PPS final rule to apply for all the years in which an adjustment is appropriate, and described most recently in the CY 2024 HH PPS final rule (88 FR 77687 through 77688), as well as the two new assumptions related to the OASIS-E mapping in the CY 2025 HH PPS final rule (89 FR 88360 through 88365), we simulated 60-day episodes using actual CY 2024 30-day periods to

³ https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/home_health_pps_lds.

⁴ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices>.

² The current expiration date for this information collection request is December 31, 2027.

determine what the proposed permanent and temporary payment adjustments should be to offset for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes.

Using the preliminary CY 2024 dataset, we began with 8,118,120 30-day periods of care and dropped 446,458 30-day periods of care that had a claim occurrence code 50 date after October 31, 2024. We also excluded 842,735 30-day periods of care that had a claim occurrence code 50 date before January 1, 2025, to ensure the 30-day period will not be part of a simulated 60-day episode that began in CY 2024. Applying the additional exclusions and assumptions as described in the finalized methodology (87 FR 66804), an additional 4,017 30-day periods were excluded.

Additionally, we excluded 211,772 simulated 60-day episodes, which consist of 391,799 30-day periods of care where no OASIS information was available in the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC), a recent start of care/resumption of care (SOC/ROC) OASIS was not available, a wage index was not available, or the episode could not be grouped to a Health Insurance Prospective Payment System (HIPPS) code due to a missing primary diagnosis or other reason. Our simulated 60-day

episodes of care produced a distribution of two 30-day periods of care (69.5 percent) and single 30-day periods of care (30.5 percent) that was similar to what we found when we simulated two 30-day periods of care for implementation of the PDGM. After all exclusions and assumptions were applied, the final dataset for this proposed rule included 6,433,111 actual 30-day periods of care and 3,794,744 simulated 60-day episodes of care for CY 2024.

Using the preliminary dataset for CY 2024 (6,433,111 actual 30-day periods which made up the 3,794,744 simulated 60-day episodes) we determined the estimated aggregate expenditures under the pre-PDGM HH PPS were lower than the actual estimated aggregate expenditures under the PDGM HH PPS. As shown in table 15, aggregate expenditures under the PDGM were higher than if the 153-group payment system were still in place in CY 2024 and therefore, we determined the CY 2024 30-day base payment rate should have been \$1,916.77 based on actual behavior changes.

As stated in the CY 2025 HH PPS final rule (89 FR 88367) we determined for CYs 2020 through CY 2023 a total of – 3.95 percent permanent adjustment was needed (after accounting for the – 3.925 percent applied to the CY 2023 payment rate and the – 2.890 applied to the CY 2024 payment rate). In order to determine behavior changes only to CY

2024, we simulated what the CY 2024 base payment rate would have been if the – 3.95 percent adjustment that we determined using CY 2023 claims data had been implemented.

To do so, we started with the recalculated CY 2023 base payment of \$1,875.46 (as published in the CY 2025 HH PPS final rule (89 FR 88366)) and applied the CY 2024 case-mix weights recalibration neutrality factor (1.0124), the CY 2024 wage index budget neutrality factor (1.0012), the CY 2024 labor-related share budget neutrality factor (0.9998), and the CY 2024 home health payment update factor (1.030). We determined the CY 2024 base payment rate for assumed behavior would have been \$1,957.63.

For the CY 2024 annual permanent adjustment, we calculated the percent change between the two payment rates for only CY 2024. For the CY 2024 annual temporary adjustment we calculated the difference in aggregate expenditures in dollars for all CY 2024 PDGM 30-day claims using the two payment rates. This difference is shown as the retrospective dollar amount we will need to offset payment using one or more temporary adjustments in future years. Our results for the CY 2024 annual (single year) permanent and temporary adjustment calculations using CY 2024 preliminary claims data is shown in table 15.

TABLE 15: CY 2024 PROPOSED PERMANENT AND TEMPORARY ADJUSTMENT CALCULATIONS

	Budget-neutral 30-day Payment Rate with Assumed Behavior Changes	Budget-neutral 30-day Payment Rate with Actual Behavior Changes	CY 2024 Only Adjustment
Base Payment Rate	\$1,957.63*	\$1,916.77	Permanent –2.087%
Aggregate Expenditures	\$16,237,950,874**	\$15,397,801,406	Temporary –\$840,149,468

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW March 13, 2025.

*The \$1,957.63 (shown in table 15) is equal to the recalculated budget neutral 30-day base payment rate of \$1,875.46 for CY 2023 multiplied by the CY 2024 recalibration factor (1.0124), CY 2024 wage index budget neutrality factor (1.0012), CY 2024 labor-related share budget neutrality factor (0.9998), and the CY 2024 home health payment update factor (1.030).

**The estimated aggregate expenditures for assumed behavior (\$16.2 billion), uses the actual CY 2024 payment rate of \$2,038.13 as finalized in the CY 2024 HHA PPS final rule (88 FR 77746).

As shown in table 15, a permanent prospective adjustment of – 2.087 percent to the CY 2026 30-day payment rate (assuming all adjustments from prior years were applied) for CY 2024 would be required to offset for such increases in estimated aggregate expenditures in future years. We remind

readers, the permanent prospective adjustment of – 2.087 percent is for illustrative purposes only and the annual (single year) permanent adjustment cannot be added to previous annual adjustments.

As shown in table 15, we determined that our initial estimate of the CY 2024

base payment rate (\$2,038.13) resulted in excess expenditures of approximately \$840 million in CY 2024.

Section 1895(b)(3)(D)(ii) of the Act requires us to annually analyze data from CY 2020 through CY 2026. We now have five years of claims data (CYs 2020 through 2024) under the PDGM,

and we have applied three partial permanent adjustments to the 30-day payment rate (CYs 2023 through 2025), which we summarize in table 16. We remind readers these annual adjustments cannot be added or

multiplied together to determine the total permanent adjustment needed for CY 2026 because each individual year requires an assumption that all prior adjustments were taken. We remind readers that equation may result in

slightly different results due to the underlying assumptions (for example, all prior year adjustments were taken) each year and rounding.

TABLE 16: TOTAL ANNUAL PERMANENT ADJUSTMENT FOR DISCRETE CLAIMS IN CYs 2020 - 2024

Claims Data	Annual Permanent Adjustment	HH PPS Final Rule Citation
CY 2020	-6.52%	87 FR 66805
CY 2021	-1.42%	87 FR 66806
CY 2022	-1.767%	88 FR 77692
CY 2023	-1.004%	89 FR 88366
CY 2024	-2.087%	TBD

Note: These annual permanent adjustments are for illustrative purposes only and are not what was implemented.

f. CY 2026 Proposed Permanent Adjustment and Temporary Adjustment Calculations

In the preceding section we describe how we annually analyzed CY 2024 preliminary claims data to determine the effects of actual behavior change on estimated aggregate expenditures. Again, that analysis included simulations that assumed the full – 3.95 percent payment adjustment was already taken. We note that CMS implemented a payment adjustment of – 1.975 percent for CY 2024, rather than the – 3.95 percent we calculated (89 FR 88373), so the calculations set forth later in this section reflect the remaining adjustments that are still needed.

Therefore, the calculation in this section includes any of the remaining adjustments not applied in previous years (that is, CYs 2020 through 2023 claims data), as well as the adjustment needed to account for CY 2024 claims. In calculating the full permanent adjustment needed to the CY 2026 30-day payment rate, we compare estimated aggregate expenditures under the PDGM and the prior system. Unlike the annual adjustments described in table 16, we do not assume the full adjustment from prior years had been taken.

As discussed in section II.C.1.d. of this proposed rule, using the preliminary dataset for CY 2024 (6,433,111 actual 30-day periods which

made up the 3,794,744 simulated 60-day episodes) we determined the CY 2024 30-day base payment rate should have been \$1,916.77 based on actual behavior. We then compared the \$1,916.77 CY 30-day base payment rate based on actual behavior to the CY 2024 30-day base payment rate of \$2,038.13 we paid based on assumed behaviors. The percent change, as summarized in table 17, between the actual CY 2024 base payment rate of \$2,038.13 (based on assumed behaviors) and the CY 2024 recalculated base payment rate of \$1,916.77 (based on actual behaviors) is the total permanent adjustment reflecting CYs 2020 through 2024 claims.

TABLE 17: TOTAL PERMANENT ADJUSTMENT FOR CYs 2020 THROUGH 2024 CLAIMS

Actual CY 2024 Base Payment Rate (Assumed Behavior)	Recalculated CY 2024 Base Payment Rate (Actual Behavior)	Total Permanent Prospective Adjustment
\$2,038.13	\$1,916.77	-5.954%*

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW March 13, 2025.
*This is the total permanent adjustment based on CY 2024 data which includes the previous permanent adjustment of -2.89% applied. However, as described later, we recognize that for CY 2026 we must also account for adjustment made in CY 2025.

As shown in table 17 a permanent prospective adjustment of – 5.954 percent to the CY 2026 30-day payment

rate would be required to offset for such increases in estimated aggregate

expenditures in future years. To illustrate this calculation:

$$\frac{(\$1,916.77 - \$2,038.13)}{\$2,038.13} = -5.954 \%$$

As we stated in the CY 2025 HH PPS final rule (89 FR 88373), applying a –1.975 percent (half of the proposed –3.95 percent) permanent adjustment to the CY 2025 30-day payment rate would not adjust the rate fully to account for differences in behavior changes on estimated aggregate expenditures in CYs 2020, 2021, 2022, and 2023. Using CY 2024 claims data, as shown in table 17, a permanent prospective adjustment of –5.954 percent to the CY 2026 30-day payment rate would be required to offset for such increases in estimated aggregate expenditures for CYs 2020 through 2024. We remind readers adjustment factors are multiplied in this payment system and, individual numbers (that is, percentages) cannot be added or subtracted together to determine the final adjustment. Therefore, we cannot determine the CY 2026 proposed permanent adjustment, which would include estimated aggregate expenditures in CY 2024, by simply subtracting the –1.975 percent applied in CY 2025 from the total permanent

adjustment of –5.954 percent as shown in table 17.

Instead, we account for the permanent adjustment applied in CY 2025 of –1.975 percent when we calculate the CY 2026 permanent adjustment by solving the following equation $(1 - 0.01975) \times (1 \times -) = (1 - 0.05954)$. To illustrate this calculation we used the following approach.

$$x = 1 - \left(\frac{1 - 0.05954}{1 - 0.01975} \right)$$

$$x = 1 - 0.95941$$

$$x = 0.04059 \text{ (that is, 4.059 percent)}$$

Accounting for the previous permanent adjustments applied to the 30-day payment rate in CYs 2023, 2024, and 2025, we can simulate the permanent adjustment calculation with the simulated annual permanent adjustment percentage shown previously for CY 2026:

Annual Permanent Adjustments

Calculated:⁵

CY 2020 Claims = –6.52% (87 FR 66805)

CY 2021 Claims = –1.42% (87 FR 66806)

CY 2022 Claims = –1.767% (88 FR 77692)

CY 2023 Claims = –1.004% (89 FR 88366)

CY 2024 Claims = –2.087% (Table 16)

Permanent Adjustments Applied:

CY 2023 Rate = –3.925% (88 FR 66808)

CY 2024 Rate = –2.890% (88 FR 77697)

CY 2025 Rate = –1.975% (89 FR 88373)

Illustrative equation.

$$(1 - 0.0652)(1 - 0.0142)(1 - 0.01767)$$

$$(1 - 0.01004)(1 - 0.02087) =$$

$$(1 - 0.03925)(1 - 0.0289)$$

$$(1 - 0.01975)(1 - x)$$

Solving, $x = 4.059\%$.

In table 18, we provide the base payment rate for assumed behaviors (what CMS actually paid), the recalculated base payment rate for actual behaviors (what CMS should have paid), the total permanent adjustments calculated from the base payment rates (accounts for any adjustments taken prior), and the permanent adjustment applied.

**TABLE 18: SUMMARY OF PERMANENT ADJUSTMENTS
FOR CYs 2020 – 2026**

Claims Analysis Year	Base Payment Rate for Assumed Behaviors (Actual Amount Paid to HHAs in the Claims Analysis Year)	Base Payment Rate that Reflects Actual Behavior Changes (As Determined After Later Claims Analysis)	Total Permanent Adjustment Between Assumed and Actual Behavior Rates*	Permanent Adjustment CMS Finalized and Implemented in Rulemaking
CY 2020	\$1,864.03	\$1,742.52	-6.52%	n/a
CY 2021	\$1,901.12	\$1,751.90	-7.85%	-3.925% (88 FR 66808)
CY 2022	\$2,031.64	\$1,839.10	-5.78%	-2.890% (88 FR 77697)
CY 2023	\$2,010.69	\$1,873.17	-3.95%	-1.975% (89 FR 88373)
CY 2024	\$2,038.13	\$1,916.77	Proposed -4.059%	-4.059% proposed to be applied to CY 2026 rates
CY 2025	TBD	TBD	TBD	TBD
CY 2026	TBD	TBD	TBD	TBD

Note: With the prospective payment systems, the claims data analyzed differ from the rulemaking cycle. For example, CY 2020 claims are used in CY 2022 rulemaking.

*The total permanent adjustment accounts for prior adjustments that were finalized and implemented through rulemaking.

In the CY 2023, 2024, and 2025 HH PPS final rules (87 FR 66790, 88 FR 77696, 89 FR 88373), we acknowledged that the full permanent adjustment in a single year may be burdensome for some providers. As shown in table 18, we finalized only half of the permanent adjustment percentages in CYs 2023

through 2025 final rules. However, we explained in the CY 2023, 2024, and 2025 HH PPS final rules (87 FR 66808, 88 FR 77697, 89 FR 88373) that when we apply a reduced permanent adjustment, we may need to continue to implement a reduction in future years to satisfy the statutory requirements.

However, we recognize that only applying half of the calculated permanent adjustments in previous years has contributed to the significant growth of the temporary adjustment. Therefore, we believe it to be appropriate to propose the full permanent adjustment to help mitigate

⁵ The annual permanent adjustments are for illustrative purposes only and the annual (single

year) permanent adjustments cannot be combined

to calculate the total permanent adjustment proposed and finalized in rulemaking.

this continued accrual of the temporary adjustment. Therefore, we are proposing to apply the full permanent adjustment of –4.059 percent to the CY 2026 home health base payment rate, noting that we expect to make minor adjustments to this percentage in the final rule using more complete claims data. Proposing the full permanent adjustment would satisfy the statutory requirements at section 1895(b)(3)(D)(ii) of the Act to offset any increases or decreases on the impact of differences between assumed behavior and actual behavior changes on estimated aggregate expenditures, reduce the need for any future large permanent adjustments, and help slow

the accrual of the temporary payment adjustment amount.

As described previously in this proposed rule, to account for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes in any given year from 2020 to 2026, we calculate one or more temporary prospective adjustments by calculating the dollar amount difference between the estimated aggregate expenditures from all 30-day periods using the recalculated 30-day base payment rate, and the aggregate expenditures for all 30-day periods using the actual 30-day base payment

rate for that year. In other words, when determining the temporary retrospective dollar amount, we used the full dataset of actual 30-day periods using both the actual and recalculated 30-day base payment rates to ensure that the utilization and distribution of claims are the same. We refer readers to the CY 2024 HH PPS final rule (88 FR 77689 through 77694) for analysis of CYs 2020 through 2022 claims, the CY 2025 HH PPS final rule (89 FR 88366 through 88369) for analysis of CY 2023 claims, and section II.C.1.d. of this proposed rule for the analysis of CY 2024 claims. Table 19 provides a summary of the temporary adjustment dollar amount for CYs 2020 through 2026.

TABLE 19: SUMMARY OF TEMPORARY ADJUSTMENTS DOLLAR AMOUNTS FOR CYS 2020 – 2026

Claims Analysis Year	Dollar Amount
CY 2020	-\$873,073,121
CY 2021	-\$1,211,002,953
CY 2022	-\$1,405,447,290
CY 2023	- \$971,431,113
CY 2024 – this proposed rule	- \$840,149,468
CY 2025	TBD
CY 2026	TBD
Total (through CY 2024)	-\$5,301,103,945

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW July 12, 2021. CY 2021 Home Health Claims Data, Periods that end in CY 2021 accessed on the CCW July 15, 2022. CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed on CCW July 15, 2023. CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on CCW July 11, 2024. CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on CCW March 13, 2025.

Note: The anticipated temporary adjustments of approximately \$5.3 billion (through CY 2024) will require temporary adjustment(s) to the base payment rate to offset for such increases in estimated aggregate expenditures. The dollar amount will be converted to a factor when implemented in future rulemaking.

Our analysis continues to show estimated aggregate expenditures are higher under the PDGM than if those same claims were paid under the prior 153-group system, though the data also show that the behavioral adjustment we implemented in CY 2023 and CY 2024 successfully brought estimated aggregate expenditures closer to the statutorily required budget neutrality. In the CY 2022 HH PPS proposed rule (86 FR 65884), the CY 2023 HH PPS proposed rule (87 FR 37608), the CY 2024 HH PPS proposed rule (88 FR 43664), the CY 2025 HH PPS proposed rule (89 FR 55320), and as shown in section II.B.1.b. of this proposed rule, our analysis has shown that the annual national standardized 30-day period payment rate has exceeded the average estimated

30-day period cost. In addition, MedPAC has continued to find that FFS Medicare’s payments for home health care are substantially in excess of costs.⁶

Given these facts, we believe that it is an appropriate time to begin recoupment of the temporary dollar amounts. Even though we have not yet calculated the temporary dollar amounts for CYs 2025 through 2026, we have done so for CYs 2020 through 2024, and the amounts are substantial. Beginning to adjust the base payment rate now to account for the calculated temporary dollar amount to date may help reduce the need for a larger reduction in future years. We estimate that collecting the

full temporary dollar amount of \$5,301,103,945 in a single year (as shown in table 19) would require an approximate 34 percent reduction to the CY 2026 base payment rate. And we anticipate that we would need to make additional adjustments for CYs 2025 and 2026, once data for those years are available.

We have stated in past rules that implementing both the permanent and temporary adjustments in the same year may be burdensome to HHAs; however, we propose only to implement a small temporary adjustment (rather than the estimated 34 percent) along with the permanent adjustment, which should lessen any hardship to HHAs, as well as reduce larger temporary adjustments in future years. Beginning to apply a

⁶ https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch7_MedPAC_Report_To_Congress_SEC.pdf.

temporary adjustment in CY 2026 balances the underlying statutory goal of budget neutrality against any hardship to HHAs.

Therefore, we exercise our authority under section 1895(b)(3)(D)(iii) of the Act to apply “one or more” temporary adjustments to begin recoupment of the retrospective overpayments for CYs 2020 through 2024. Specifically, we propose to implement a 5.0 percent reduction in CY 2026, that is equivalent to a 0.9500 temporary adjustment factor, to the CY 2026 national, standardized payment rate. Using historical trends, we estimated 7,723,632 number of 30-day periods would occur in CY 2026. Using this estimated utilization, a 5.0 percent reduction to the CY 2026 30-day payment rate would begin to collect approximately \$786 million of the total temporary adjustment dollar amount, equating to about 14.8 percent of the total \$5.3 billion shown in table 19. In doing so, however, we would need to account for the remaining temporary adjustment dollar amount for CYs 2020 through 2024, plus any possible adjustments for CY 2025 and 2026, in future years. It is important to note that the estimated \$786 million dollar amount anticipated to be collected by the implementation of the temporary adjustment factor is based on an estimate of the number of 30-day periods that would occur in CY 2026. It may not reflect the actual dollar amount to be collected if the actual number of 30-day periods and other utilization trends in CY 2026 differ from what was estimated. In other words, CMS will calculate the actual amount collected from the temporary adjustment in CY 2026 and credit it to the overall cumulative temporary dollar amount.

In accordance with section 1895(b)(3)(D)(iii) of the Act, the temporary adjustment is to be applied on a prospective basis and shall apply only with respect to the year for which such temporary increase or decrease is made. We interpret this to mean we would not include the –5.0 percent temporary adjustment applied for CY 2026 when calculating the CY 2027 base payment rates. However, to continue recoupment of the retrospective overpayments we may propose additional temporary adjustments in future rulemaking and are not proposing that the –5.0 percent temporary adjustment would be applied each year after CY 2026. Rather, we will continue to analyze the data each year through CY 2026 claims as required by law, and in a time and manner deemed appropriate we will propose one or more temporary adjustments to account for retrospective overpayments. We refer

readers to section II.E.3.b. for the CY 2026 base payment rates with and without the temporary adjustment.

We solicit comments on the proposals to apply the permanent adjustment of –4.059 percent and the –5.0 percent temporary adjustment to the CY 2026 home health base payment rate.

D. Proposed CY 2026 Home Health Low Utilization Payment Adjustment (LUPA) Thresholds, Functional Impairment Levels, Comorbidity Sub-Groups, and Case-Mix Weights

1. Proposed CY 2026 PDGM LUPA Thresholds

Under the HH PPS, LUPAs are paid when a certain numerical minimum visit threshold for a payment group during a 30-day period of care is not met. In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized a policy setting the LUPA thresholds at the 10th percentile of visits or two visits, whichever is higher, for each payment group. This means the LUPA threshold for each 30-day period of care varies depending on the PDGM payment group to which it is assigned. If the LUPA threshold for the payment group is met under the PDGM, the 30-day period of care would be paid the full 30-day period case-mix adjusted payment amount (subject to any partial payment adjustment or outlier adjustments). If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment would be made using the per-visit payment amounts as described in section II.E.3.c. of this proposed rule. For example, if the LUPA visit threshold is four, and a 30-day period of care has four or more visits, it is paid the full 30-day period payment amount; if the period of care has three or fewer visits, payment is made using the per-visit payment amounts.

In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized our policy that the LUPA thresholds for each PDGM payment group will be reevaluated every year based on the most current utilization data available at the time of rulemaking. However, as CY 2020 was the first year of the new case-mix adjustment methodology, we stated in the CY 2021 HH PPS final rule (85 FR 70305, 70306) that we would maintain the LUPA thresholds that were finalized and shown in table 17 of the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2021 payment purposes. We stated that at that time, we did not have sufficient CY 2020 data to reevaluate the LUPA thresholds for CY 2021.

In the CY 2022 HH PPS final rule with comment period (86 FR 62249), we finalized the proposal to recalibrate the PDGM case-mix weights, functional impairment levels, and comorbidity subgroups while maintaining the LUPA thresholds for CY 2022. We stated that because there are several factors that contribute to how the case-mix weight is set for a particular case-mix group (such as the number of visits, length of visits, types of disciplines providing visits, and non-routine supplies) and the case-mix weight is derived by comparing the average resource use for the case-mix group relative to the average resource use across all groups, we believe the COVID–19 public health emergency (PHE) will have impacted utilization within all case-mix groups similarly. Therefore, the impact of any reduction in resource use caused by the PHE on the calculation of the case-mix weight will be minimized since the impact will be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight. However, in contrast, the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (like what is used to generate the case-mix weight) that will control for the impacts of the COVID–19 PHE. We noted that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. Therefore, to mitigate any potential future and significant short-term variability in the LUPA thresholds due to the COVID–19 PHE, we finalized the proposal to maintain the LUPA thresholds finalized and displayed in table 17 in the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2022 payment purposes.

For CY 2024, we proposed to update the LUPA thresholds using CY 2022 Medicare home health claims (as of March 17, 2023) linked to OASIS assessment data. We believed that CY 2022 data would be more indicative of visit patterns in CY 2024 rather than continuing to use the LUPA thresholds derived from the CY 2018 pre-PDGM data. Therefore, we finalized a policy to update the LUPA thresholds for CY 2024 using data from CY 2022.

For CY 2026, we are proposing to update the LUPA thresholds using CY 2024 home health claims utilization data (as of March 13, 2025), in accordance with our policy to annually recalibrate the case-mix weights and update the LUPA thresholds, functional impairment levels, and comorbidity

subgroups. After reviewing the CY 2024 home health claims utilization data, we determined that LUPA visit patterns in 2024 were similar to visits in 2023 and a total of 15 case-mix groups have a decline in their LUPA threshold of a single visit and 4 case-mix groups have their LUPA threshold increase by a single visit. The proposed LUPA thresholds for the CY 2026 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in table 25.

We are soliciting public comments on the proposed updates to the LUPA thresholds for CY 2026. The proposed LUPA thresholds will be updated based on more complete CY 2024 claims data in the final rule.

2. Proposed CY 2026 Functional Impairment Levels

Under the PDGM, the functional impairment level is determined by responses to certain OASIS items associated with activities of daily living

and risk of hospitalization; that is, responses to OASIS items M1800–M1860 and M1033. A home health period of care receives points based on each of the responses associated with these functional OASIS items, which are then converted into a table of points corresponding to increased resource use. The sum of all these points results in a functional impairment score which is used to group home health periods into a functional level with similar resource use. That is, the higher the points, the more the response is associated with increased resource use, or increased impairment. The three functional impairment levels of low, medium, and high were designed so that approximately one-third of home health periods from each clinical group falls within each level. This means home health periods in the low impairment level have responses for the functional OASIS items that are associated with the lowest resource use, on average. Home health periods in the high

impairment level have responses for the functional OASIS items that are associated with the highest resource use on average.

For CY 2026, we are proposing to use CY 2024 claims data to update the functional points and functional impairment levels by clinical group. The CY 2018 HH PPS proposed rule (82 FR 35320) and the technical report from December 2016, posted on the Home Health PPS Archive web page, located at <https://www.cms.gov/medicare/home-health-pps/home-health-pps-archive>, provides a more detailed explanation as to the construction of the functional impairment levels using the OASIS items. We are proposing to use the same methodology previously finalized to update the functional impairment levels for CY 2026. The proposed updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2026 are listed in tables 20 and 21, respectively.

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TABLE 20: PROPOSED OASIS POINTS TABLE FOR CY 2026

	Responses	CY 2026 Proposed Points	Percent of Periods with this Response Category*
M1800: Grooming	0 or 1	0	23.2%
	2 or 3	3	76.8%
M1810: Current Ability to Dress Upper Body	0 or 1	0	17.6%
	2 or 3	5	82.4%
M1820: Current Ability to Dress Lower Body	0 or 1	0	8.5%
	2	4	64.2%
	3	12	27.3%
M1830: Bathing	0 or 1	0	2.2%
	2	2	9.3%
	3 or 4	10	48.7%
	5 or 6	17	39.8%
M1840: Toilet Transferring	0 or 1	0	59.4%
	2, 3 or 4	6	40.6%
M1850: Transferring	0	0	1.0%
	1	1	17.2%
	2, 3, 4 or 5	4	81.8%
M1860: Ambulation/Locomotion	0 or 1	0	2.8%
	2	5	13.0%
	3	1	66.3%
	4, 5 or 6	20	17.8%
M1033: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	0	56.4%
	Four or more items marked (Excluding responses 8, 9 or 10)	12	43.6%

Source: Percent of periods in 2024 with this response category using CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed from the CCW on March 13, 2025.

Note: For item M1860, the point values for response 2 is worth more than the point values for response 3. There may be times in which the resource use for certain OASIS items associated with functional impairment will result in a seemingly inverse relationship to the response reported. However, this is the result of the direct association between the responses reported on the OASIS items and actual resource use.

TABLE 21: PROPOSED THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, FOR CY 2026

Clinical Group	Level of Impairment	CY 2026 Proposed Points
MMTA – Other	Low	0-30
	Medium	31-45
	High	46+
Behavioral Health	Low	0-31
	Medium	32-46
	High	47+
Complex Nursing Interventions	Low	0-31
	Medium	32-54
	High	55+
Musculoskeletal Rehabilitation	Low	0-31
	Medium	32-45
	High	46+
Neuro Rehabilitation	Low	0-34
	Medium	35-52
	High	53+
Wound	Low	0-33
	Medium	34-52
	High	53+
MMTA - Surgical Aftercare	Low	0-30
	Medium	31-42
	High	43+
MMTA - Cardiac and Circulatory	Low	0-28
	Medium	29-43
	High	44+
MMTA - Endocrine	Low	0-27
	Medium	28-41
	High	42+
MMTA - Gastrointestinal tract and Genitourinary system	Low	0-34
	Medium	35-48
	High	49+
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	0-32
	Medium	33-46
	High	47+
MMTA - Respiratory	Low	0-33
	Medium	34-46
	High	47+

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed from the CCW on March 13, 2025.

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We are soliciting public comments on the proposed updates to functional points and the functional impairment levels by clinical group.

3. Proposed CY 2026 Comorbidity Subgroups

Thirty-day periods of care receive a comorbidity adjustment category based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a

home-health specific list of clinically and statistically significant secondary diagnosis subgroups with similar resource use, meaning the diagnoses have at least as high as the median resource use and are reported in more than 0.1 percent of 30-day periods of care. Home health 30-day periods of care can receive a comorbidity adjustment under the following circumstances:

- *High comorbidity adjustment:* There are two or more secondary diagnoses on the home health-specific comorbidity subgroup interaction list that are associated with higher resource use when both are reported together compared to when they are reported separately. That is, the two diagnoses may interact with one another, resulting in higher resource use.
- *Low comorbidity adjustment:* There is a reported secondary diagnosis on the

home health-specific comorbidity subgroup list that is associated with higher resource use.

- *No comorbidity adjustment:* A 30-day period of care receives no comorbidity adjustment if no secondary diagnoses exist or do not meet the criteria for a low or high comorbidity adjustment.

In the CY 2019 HH PPS final rule with comment period (83 FR 56406), we stated that we will continue to examine the relationship of reported comorbidities on resource utilization and make the appropriate payment refinements to help ensure that payment is in alignment with the actual costs of

providing care. For CY 2026, we are proposing to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using CY 2024 home health data with linked OASIS data (as of March 13, 2025).

For CY 2026, we are proposing to update the comorbidity subgroups to include 20 low comorbidity adjustment subgroups and 100 high comorbidity adjustment interaction subgroups. The proposed CY 2026 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity

adjustments are shown in tables 22 and 23. The proposed CY 2026 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments will also be posted on the HHA Center web page at <https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center>.

We invite comments on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment interactions for CY 2026.

TABLE 22: LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2026

Low Comorbidity Subgroup	Description
Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
Circulatory 10	Varicose Veins and Lymphedema
Circulatory 9	Other Venous Embolism and Thrombosis
Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
Gastrointestinal 2	Intestinal Obstruction and Ileus
Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
Heart 11	Heart Failure
Heart 5	Atherosclerotic Heart Disease with Angina
Musculoskeletal 1	Lupus
Neoplasms 1	Malignant Neoplasms of Lip, Oral Cavity and Pharynx, includes Head and Neck Cancers
Neoplasms 17	Secondary neoplasms of respiratory and GI systems.
Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
Neoplasms 6	Malignant neoplasms of trachea, bronchus, lung, and mediastinum
Neurological 10	Diabetes with neuropathy
Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW March 13, 2025.

TABLE 23: HIGH COMORBIDITY ADJUSTMENT INTERACTIONS FOR CY 2026

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
1	Heart 12	Other Heart Diseases	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
2	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
3	Heart 11	Heart Failure	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
4	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Endocrine 1	Hypothyroidism
5	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neoplasms 17	Secondary neoplasms of respiratory and GI systems.
6	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Circulatory 9	Other Venous Embolism and Thrombosis
7	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Circulatory 10	Varicose Veins and Lymphedema
8	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
9	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
10	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
		Atherosclerosis and Stroke Sequelae		
11	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Heart 12	Other Heart Diseases
12	Circulatory 9	Other Venous Embolism and Thrombosis	Musculoskeletal 4	Lumbar Spinal Stenosis
13	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Heart 11	Heart Failure
14	Circulatory 9	Other Venous Embolism and Thrombosis	Heart 11	Heart Failure
15	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 10	Diabetes with neuropathy
16	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Infectious 1	C-diff, MRSA, E-coli
17	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Neurological 8	Epilepsy
18	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
19	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Respiratory 2	Whooping cough
20	Circulatory 10	Varicose Veins and Lymphedema	Heart 9	Valve Disorders
21	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 10	Diabetes with neuropathy

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
22	Renal 1	Chronic kidney disease and ESRD	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
23	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
24	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
25	Circulatory 9	Other Venous Embolism and Thrombosis	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
26	Circulatory 4	Hypertensive Chronic Kidney Disease	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
27	Neoplasms 17	Secondary neoplasms of respiratory and GI systems.	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
28	Neurological 12	Nondiabetic neuropathy	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
29	Heart 11	Heart Failure	Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
30	Circulatory 4	Hypertensive Chronic Kidney Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
31	Endocrine 1	Hypothyroidism	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
32	Circulatory 10	Varicose Veins and Lymphedema	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
33	Endocrine 1	Hypothyroidism	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
34	Circulatory 10	Varicose Veins and Lymphedema	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
35	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Circulatory 10	Varicose Veins and Lymphedema
36	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
37	Circulatory 10	Varicose Veins and Lymphedema	Renal 1	Chronic kidney disease and ESRD
38	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
39	Heart 7	Chronic Ischemic Heart Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
40	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
41	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
42	Infectious 1	C-diff, MRSA, E-coli	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
43	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
44	Neurological 4	Alzheimer's disease and related dementias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
45	Heart 11	Heart Failure	Neoplasms 17	Secondary neoplasms of respiratory and GI systems.
46	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
47	Heart 12	Other Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
48	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
49	Circulatory 10	Varicose Veins and Lymphedema	Musculoskeletal 4	Lumbar Spinal Stenosis

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
50	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Respiratory 4	Bronchitis, Emphysema, and Interstitial Lung Disease
51	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 3	Diseases of arteries, arterioles and non-pressure chronic ulcers
52	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
53	Infectious 1	C-diff, MRSA, E-coli	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
54	Circulatory 10	Varicose Veins and Lymphedema	Heart 8	Other Pulmonary Heart Diseases
55	Circulatory 10	Varicose Veins and Lymphedema	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
56	Circulatory 10	Varicose Veins and Lymphedema	Neurological 10	Diabetes with neuropathy
57	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 1	Hypothyroidism
58	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance
59	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
60	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 3	Diseases of arteries, arterioles and non-pressure chronic ulcers
61	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of arteries, arterioles and non-pressure chronic ulcers
62	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 3	Diseases of arteries, arterioles and non-pressure chronic ulcers

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
63	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
64	Neurological 10	Diabetes with neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
65	Heart 8	Other Pulmonary Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
66	Musculoskeletal 3	Joint Pain	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
67	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
68	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
69	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
70	Infectious 1	C-diff, MRSA, E-coli	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
71	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
72	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
73	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
74	Neurological 10	Diabetes with neuropathy	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
75	Respiratory 9	Respiratory Failure and Atelectasis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
76	Heart 11	Heart Failure	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
77	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
78	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
79	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
80	Circulatory 10	Varicose Veins and Lymphedema	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
81	Neurological 12	Nondiabetic neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
82	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
83	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
84	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
85	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
86	Renal 1	Chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
87	Musculoskeletal 3	Joint Pain	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
88	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
89	Heart 11	Heart Failure	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
90	Respiratory 2	Whooping cough	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
91	Circulatory 10	Varicose Veins and Lymphedema	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
92	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
93	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
94	Heart 8	Other Pulmonary Heart Diseases	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
95	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
96	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
97	Infectious 1	C-diff, MRSA, E-coli	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
98	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
99	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
100	Circulatory 9	Other Venous Embolism and Thrombosis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Source: CY 2024 Home Health Claims Data. Periods that end in CY 2024 accessed from the CCW March 13, 2025.

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4. Proposed CY 2026 PDGM Case-Mix Weights

As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56502), the PDGM places patients into

meaningful payment categories based on patient and other characteristics, such as timing, admission source, clinical grouping using the reported principal diagnosis, functional impairment level, and comorbid conditions. The PDGM case-mix methodology results in 432

unique case-mix groups called home health resource groups (HHRGs). We also finalized a policy in the CY 2019 HH PPS final rule with comment period (83 FR 56515) to annually recalibrate the PDGM case-mix weights using a fixed effects model with the most recent

and complete utilization data available at the time of annual rulemaking. Annual recalibration of the PDGM case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns. To generate the proposed recalibrated CY 2026 case-mix weights, we used CY 2024 home health claims data with linked OASIS data (as of March 13, 2025). These data are the most current and complete data available at the time of rulemaking. We believe that recalibrating the case-mix weights using data from CY 2024 would be reflective of PDGM utilization and patient resource use for CY 2026. The proposed recalibrated case-mix weights will be updated in the final rule based on more complete CY 2024 claims data.

The claims data provide visit-level data and data on whether non-routine supplies (NRS) were provided during the period and the total charges of NRS. We determine the case-mix weight for each of the 432 different PDGM payment groups by regressing resource use on a series of indicator variables for each of the categories using a fixed effects model as described in the following steps:

Step 1: Estimate a regression model to assign a functional impairment level to each 30-day period. The regression model estimates the relationship between a 30-day period's resource use and the functional status and risk of hospitalization items included in the PDGM, which are obtained from certain OASIS items. We refer readers to table 20 for further information on the OASIS items used for the functional impairment level under the PDGM. We measure resource use with the cost-per-minute + NRS approach that uses information from 2023 home health cost reports. We use 2023 home health cost report data because it is the most complete cost report data available at the time of rulemaking. Other variables in the regression model include the 30-day period's admission source, clinical

group, and 30-day period timing. We also include home health agency level fixed effects in the regression model. After estimating the regression model using 30-day periods, we divide the coefficients that correspond to the functional status and risk of hospitalization items by 10 and round to the nearest whole number. Those rounded numbers are used to compute a functional score for each 30-day period by summing together the rounded numbers for the functional status and risk of hospitalization items that are applicable to each 30-day period. Next, each 30-day period is assigned to a functional impairment level (low, medium, or high) depending on the 30-day period's total functional score. Each clinical group has a separate set of functional thresholds used to assign 30-day periods into a low, medium or high functional impairment level. We set those thresholds so that we assign roughly a third of 30-day periods within each clinical group to each functional impairment level (low, medium, or high).

Step 2: A second regression model estimates the relationship between a 30-day period's resource use and indicator variables for the presence of any of the comorbidities and comorbidity interactions that were originally examined for inclusion in the PDGM. Like the first regression model, this model also includes home health agency level fixed effects and includes control variables for each 30-day period's admission source, clinical group, timing, and functional impairment level. After we estimate the model, we assign comorbidities to the low comorbidity adjustment if any comorbidities have a coefficient that is statistically significant (p-value of 0.05 or less) and which have a coefficient that is larger than the 50th percentile of positive and statistically significant comorbidity coefficients. If two comorbidities in the model and their interaction term have coefficients that sum together to exceed \$150 and the

interaction term is statistically significant (p-value of 0.05 or less), we assign the two comorbidities together to the high comorbidity adjustment.

Step 3: After Step 2, each 30-day period is assigned to a clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. For each combination of those variables (which represent the 432 different payment groups that comprise the PDGM), we then calculate the 10th percentile of visits across all 30-day periods within a particular payment group. If a 30-day period's number of visits is less than the 10th percentile for their payment group, the 30-day period is classified as a Low Utilization Payment Adjustment (LUPA). If a payment group has a 10th percentile of visits that is less than two, we set the LUPA threshold for that payment group to be equal to two. That means if a 30-day period has one visit, it is classified as a LUPA and if it has two or more visits, it is not classified as a LUPA.

Step 4: Take all non-LUPA 30-day periods and regress resource use on the 30-day period's clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. The regression includes fixed effects at the level of the home health agency. After we estimate the model, the model coefficients are used to predict each 30-day period's resource use. To create the case-mix weight for each 30-day period, the predicted resource use is divided by the overall resource use of the 30-day periods used to estimate the regression.

The case-mix weight is then used to adjust the base payment rate to determine each 30-day period's payment. Table 24 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use.

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TABLE 24: COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE

Variable	Coefficient	Percentage of 30-Day Periods for this Model	Coefficient Divided by Average Resource Use
Clinical Group and Functional Impairment Level (MMTA - Other - Low is excluded)			
MMTA - Other - Medium Functional	\$153.42	1.4%	0.0891
MMTA - Other - High Functional	\$324.11	1.2%	0.1882
MMTA - Surgical Aftercare - Low Functional	-\$12.86	1.2%	-0.0075
MMTA - Surgical Aftercare - Medium Functional	\$165.33	1.2%	0.0960
MMTA - Surgical Aftercare - High Functional	\$401.81	1.2%	0.2333
MMTA - Cardiac and Circulatory - Low Functional	-\$28.68	5.9%	-0.0167
MMTA - Cardiac and Circulatory - Medium Functional	\$140.40	5.7%	0.0815
MMTA - Cardiac and Circulatory - High Functional	\$325.38	5.9%	0.1890
MMTA - Endocrine - Low Functional	\$475.82	2.5%	0.2763
MMTA - Endocrine - Medium Functional	\$555.34	2.2%	0.3225
MMTA - Endocrine - High Functional	\$689.56	2.4%	0.4004
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-\$39.79	1.8%	-0.0231
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	\$144.40	1.6%	0.0839
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	\$328.62	1.7%	0.1908
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	\$2.03	1.6%	0.0012
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	\$156.15	1.7%	0.0907
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	\$414.03	1.4%	0.2404
MMTA - Respiratory - Low Functional	-\$14.23	2.5%	-0.0083
MMTA - Respiratory - Medium Functional	\$161.84	2.4%	0.0940
MMTA - Respiratory - High Functional	\$346.62	2.2%	0.2013
Behavioral Health - Low Functional	-\$74.73	0.7%	-0.0434
Behavioral Health - Medium Functional	\$149.33	0.8%	0.0867
Behavioral Health - High Functional	\$286.04	0.7%	0.1661
Complex - Low Functional	-\$33.61	0.9%	-0.0195
Complex - Medium Functional	\$212.24	0.9%	0.1233
Complex - High Functional	\$155.09	0.9%	0.0901
MS Rehab - Low Functional	\$42.96	7.3%	0.0250
MS Rehab - Medium Functional	\$192.90	7.2%	0.1120
MS Rehab - High Functional	\$423.58	6.8%	0.2460
Neuro - Low Functional	\$199.08	3.7%	0.1156
Neuro - Medium Functional	\$381.90	3.8%	0.2218
Neuro - High Functional	\$622.08	3.4%	0.3613
Wound - Low Functional	\$730.62	4.9%	0.4243
Wound - Medium Functional	\$870.17	4.5%	0.5053
Wound - High Functional	\$1,100.15	4.6%	0.6389
Admission Source with Timing (Community Early is excluded)			
Community - Late	-\$578.23	64.0%	-0.3358

Institutional – Early		\$355.47	18.6%	0.2064
Institutional – Late		\$234.11	6.1%	0.1359
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)				
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list		\$97.67	39.3%	0.0567
Comorbidity Adjustment - Has at least one interaction from interaction list		\$332.68	18.8%	0.1932
Constant		\$1,585.49		
Average Resource Use		\$1,722.00		
Number of 30-day Periods		7,430,908		
Adjusted R-Squared		0.3089		

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW March 13, 2025.

The proposed case-mix weights for CY 2026 are listed in table 25 and will also be posted on the HHA Center web

page⁷ upon display of this proposed rule.

⁷ HHA Center web page: <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center>.

TABLE 25: CASE-MIX WEIGHTS AND LUPA THRESHOLDS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1FC11	Behavioral Health - High	Early - Community	0	1.0868	4
1FC21	Behavioral Health - High	Early - Community	1	1.1436	4
1FC31	Behavioral Health - High	Early - Community	2	1.2800	4
2FC11	Behavioral Health - High	Early - Institutional	0	1.2933	4
2FC21	Behavioral Health - High	Early - Institutional	1	1.3500	4
2FC31	Behavioral Health - High	Early - Institutional	2	1.4865	4
3FC11	Behavioral Health - High	Late - Community	0	0.7510	2
3FC21	Behavioral Health - High	Late - Community	1	0.8078	2
3FC31	Behavioral Health - High	Late - Community	2	0.9442	2
4FC11	Behavioral Health - High	Late - Institutional	0	1.2228	3
4FC21	Behavioral Health - High	Late - Institutional	1	1.2795	3
4FC31	Behavioral Health - High	Late - Institutional	2	1.4160	3
1FA11	Behavioral Health - Low	Early - Community	0	0.8773	3
1FA21	Behavioral Health - Low	Early - Community	1	0.9340	3
1FA31	Behavioral Health - Low	Early - Community	2	1.0705	3
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0838	3
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1405	3
2FA31	Behavioral Health - Low	Early - Institutional	2	1.2769	2
3FA11	Behavioral Health - Low	Late - Community	0	0.5415	2
3FA21	Behavioral Health - Low	Late - Community	1	0.5983	2
3FA31	Behavioral Health - Low	Late - Community	2	0.7347	2
4FA11	Behavioral Health - Low	Late - Institutional	0	1.0133	3
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0700	3
4FA31	Behavioral Health - Low	Late - Institutional	2	1.2065	2
1FB11	Behavioral Health - Medium	Early - Community	0	1.0074	4
1FB21	Behavioral Health - Medium	Early - Community	1	1.0642	4
1FB31	Behavioral Health - Medium	Early - Community	2	1.2006	4
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.2139	3
2FB21	Behavioral Health - Medium	Early - Institutional	1	1.2706	4
2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4071	4
3FB11	Behavioral Health - Medium	Late - Community	0	0.6717	2
3FB21	Behavioral Health - Medium	Late - Community	1	0.7284	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3FB31	Behavioral Health - Medium	Late - Community	2	0.8649	2
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1434	3
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.2001	3
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3366	4
1DC11	Complex - High	Early - Community	0	1.0108	2
1DC21	Complex - High	Early - Community	1	1.0675	2
1DC31	Complex - High	Early - Community	2	1.2040	2
2DC11	Complex - High	Early - Institutional	0	1.2172	3
2DC21	Complex - High	Early - Institutional	1	1.2739	3
2DC31	Complex - High	Early - Institutional	2	1.4104	3
3DC11	Complex - High	Late - Community	0	0.6750	2
3DC21	Complex - High	Late - Community	1	0.7317	2
3DC31	Complex - High	Late - Community	2	0.8682	2
4DC11	Complex - High	Late - Institutional	0	1.1467	2
4DC21	Complex - High	Late - Institutional	1	1.2035	2
4DC31	Complex - High	Late - Institutional	2	1.3399	2
1DA11	Complex - Low	Early - Community	0	0.9012	2
1DA21	Complex - Low	Early - Community	1	0.9579	2
1DA31	Complex - Low	Early - Community	2	1.0944	2
2DA11	Complex - Low	Early - Institutional	0	1.1076	3
2DA21	Complex - Low	Early - Institutional	1	1.1644	3
2DA31	Complex - Low	Early - Institutional	2	1.3008	3
3DA11	Complex - Low	Late - Community	0	0.5654	2
3DA21	Complex - Low	Late - Community	1	0.6221	2
3DA31	Complex - Low	Late - Community	2	0.7586	2
4DA11	Complex - Low	Late - Institutional	0	1.0372	2
4DA21	Complex - Low	Late - Institutional	1	1.0939	2
4DA31	Complex - Low	Late - Institutional	2	1.2304	3
1DB11	Complex - Medium	Early - Community	0	1.0440	2
1DB21	Complex - Medium	Early - Community	1	1.1007	2
1DB31	Complex - Medium	Early - Community	2	1.2372	2
2DB11	Complex - Medium	Early - Institutional	0	1.2504	3
2DB21	Complex - Medium	Early - Institutional	1	1.3071	3
2DB31	Complex - Medium	Early - Institutional	2	1.4436	3
3DB11	Complex - Medium	Late - Community	0	0.7082	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3DB21	Complex - Medium	Late - Community	1	0.7649	2
3DB31	Complex - Medium	Late - Community	2	0.9014	2
4DB11	Complex - Medium	Late - Institutional	0	1.1799	3
4DB21	Complex - Medium	Late - Institutional	1	1.2366	3
4DB31	Complex - Medium	Late - Institutional	2	1.3731	3
1HC11	MMTA - Cardiac - High	Early - Community	0	1.1097	4
1HC21	MMTA - Cardiac - High	Early - Community	1	1.1664	4
1HC31	MMTA - Cardiac - High	Early - Community	2	1.3029	4
2HC11	MMTA - Cardiac - High	Early - Institutional	0	1.3161	4
2HC21	MMTA - Cardiac - High	Early - Institutional	1	1.3728	4
2HC31	MMTA - Cardiac - High	Early - Institutional	2	1.5093	4
3HC11	MMTA - Cardiac - High	Late - Community	0	0.7739	2
3HC21	MMTA - Cardiac - High	Late - Community	1	0.8306	2
3HC31	MMTA - Cardiac - High	Late - Community	2	0.9671	3
4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2456	3
4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.3024	3
4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4388	3
1HA11	MMTA - Cardiac - Low	Early - Community	0	0.9041	4
1HA21	MMTA - Cardiac - Low	Early - Community	1	0.9608	3
1HA31	MMTA - Cardiac - Low	Early - Community	2	1.0973	4
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	1.1105	4
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	1.1672	4
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	1.3037	4
3HA11	MMTA - Cardiac - Low	Late - Community	0	0.5683	2
3HA21	MMTA - Cardiac - Low	Late - Community	1	0.6250	2
3HA31	MMTA - Cardiac - Low	Late - Community	2	0.7615	2
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	1.0400	3
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	1.0967	3
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	1.2332	3
1HB11	MMTA - Cardiac - Medium	Early - Community	0	1.0023	4
1HB21	MMTA - Cardiac - Medium	Early - Community	1	1.0590	4
1HB31	MMTA - Cardiac - Medium	Early - Community	2	1.1955	4
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	1.2087	4
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	1.2654	4
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	1.4019	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3HB11	MMTA - Cardiac - Medium	Late - Community	0	0.6665	2
3HB21	MMTA - Cardiac - Medium	Late - Community	1	0.7232	2
3HB31	MMTA - Cardiac - Medium	Late - Community	2	0.8597	2
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	1.1382	3
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	1.1949	3
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	1.3314	4
1IC11	MMTA - Endocrine - High	Early - Community	0	1.3212	4
1IC21	MMTA - Endocrine - High	Early - Community	1	1.3779	4
1IC31	MMTA - Endocrine - High	Early - Community	2	1.5144	4
2IC11	MMTA - Endocrine - High	Early - Institutional	0	1.5276	4
2IC21	MMTA - Endocrine - High	Early - Institutional	1	1.5843	4
2IC31	MMTA - Endocrine - High	Early - Institutional	2	1.7208	4
3IC11	MMTA - Endocrine - High	Late - Community	0	0.9854	3
3IC21	MMTA - Endocrine - High	Late - Community	1	1.0421	3
3IC31	MMTA - Endocrine - High	Late - Community	2	1.1786	3
4IC11	MMTA - Endocrine - High	Late - Institutional	0	1.4571	4
4IC21	MMTA - Endocrine - High	Late - Institutional	1	1.5138	4
4IC31	MMTA - Endocrine - High	Late - Institutional	2	1.6503	4
1IA11	MMTA - Endocrine - Low	Early - Community	0	1.1970	4
1IA21	MMTA - Endocrine - Low	Early - Community	1	1.2538	4
1IA31	MMTA - Endocrine - Low	Early - Community	2	1.3902	4
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	1.4035	3
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	1.4602	4
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	1.5967	4
3IA11	MMTA - Endocrine - Low	Late - Community	0	0.8613	3
3IA21	MMTA - Endocrine - Low	Late - Community	1	0.9180	3
3IA31	MMTA - Endocrine - Low	Late - Community	2	1.0544	3
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	1.3330	3
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	1.3897	3
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	1.5262	3
1IB11	MMTA - Endocrine - Medium	Early - Community	0	1.2432	5
1IB21	MMTA - Endocrine - Medium	Early - Community	1	1.2999	5
1IB31	MMTA - Endocrine - Medium	Early - Community	2	1.4364	4
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	1.4497	4
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	1.5064	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	1.6428	4
3IB11	MMTA - Endocrine - Medium	Late - Community	0	0.9074	3
3IB21	MMTA - Endocrine - Medium	Late - Community	1	0.9642	3
3IB31	MMTA - Endocrine - Medium	Late - Community	2	1.1006	3
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	1.3792	4
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	1.4359	4
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	1.5724	4
1JC11	MMTA - GI/GU - High	Early - Community	0	1.1116	3
1JC21	MMTA - GI/GU - High	Early - Community	1	1.1683	3
1JC31	MMTA - GI/GU - High	Early - Community	2	1.3048	2
2JC11	MMTA - GI/GU - High	Early - Institutional	0	1.3180	4
2JC21	MMTA - GI/GU - High	Early - Institutional	1	1.3747	3
2JC31	MMTA - GI/GU - High	Early - Institutional	2	1.5112	3
3JC11	MMTA - GI/GU - High	Late - Community	0	0.7758	2
3JC21	MMTA - GI/GU - High	Late - Community	1	0.8325	2
3JC31	MMTA - GI/GU - High	Late - Community	2	0.9690	2
4JC11	MMTA - GI/GU - High	Late - Institutional	0	1.2475	3
4JC21	MMTA - GI/GU - High	Late - Institutional	1	1.3042	3
4JC31	MMTA - GI/GU - High	Late - Institutional	2	1.4407	3
1JA11	MMTA - GI/GU - Low	Early - Community	0	0.8976	2
1JA21	MMTA - GI/GU - Low	Early - Community	1	0.9543	2
1JA31	MMTA - GI/GU - Low	Early - Community	2	1.0908	3
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	1.1040	3
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	1.1608	3
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	1.2972	3
3JA11	MMTA - GI/GU - Low	Late - Community	0	0.5618	2
3JA21	MMTA - GI/GU - Low	Late - Community	1	0.6185	2
3JA31	MMTA - GI/GU - Low	Late - Community	2	0.7550	2
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	1.0336	3
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	1.0903	3
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	1.2268	3
1JB11	MMTA - GI/GU - Medium	Early - Community	0	1.0046	3
1JB21	MMTA - GI/GU - Medium	Early - Community	1	1.0613	3
1JB31	MMTA - GI/GU - Medium	Early - Community	2	1.1978	3
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	1.2110	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	1.2677	3
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	1.4042	4
3JB11	MMTA - GI/GU - Medium	Late - Community	0	0.6688	2
3JB21	MMTA - GI/GU - Medium	Late - Community	1	0.7255	2
3JB31	MMTA - GI/GU - Medium	Late - Community	2	0.8620	2
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	1.1405	3
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	1.1972	3
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	1.3337	3
1KC11	MMTA - Infectious - High	Early - Community	0	1.1612	2
1KC21	MMTA - Infectious - High	Early - Community	1	1.2179	2
1KC31	MMTA - Infectious - High	Early - Community	2	1.3544	2
2KC11	MMTA - Infectious - High	Early - Institutional	0	1.3676	3
2KC21	MMTA - Infectious - High	Early - Institutional	1	1.4243	3
2KC31	MMTA - Infectious - High	Early - Institutional	2	1.5608	3
3KC11	MMTA - Infectious - High	Late - Community	0	0.8254	2
3KC21	MMTA - Infectious - High	Late - Community	1	0.8821	2
3KC31	MMTA - Infectious - High	Late - Community	2	1.0186	2
4KC11	MMTA - Infectious - High	Late - Institutional	0	1.2971	3
4KC21	MMTA - Infectious - High	Late - Institutional	1	1.3538	3
4KC31	MMTA - Infectious - High	Late - Institutional	2	1.4903	3
1KA11	MMTA - Infectious - Low	Early - Community	0	0.9219	2
1KA21	MMTA - Infectious - Low	Early - Community	1	0.9786	2
1KA31	MMTA - Infectious - Low	Early - Community	2	1.1151	2
2KA11	MMTA - Infectious - Low	Early - Institutional	0	1.1283	3
2KA21	MMTA - Infectious - Low	Early - Institutional	1	1.1851	3
2KA31	MMTA - Infectious - Low	Early - Institutional	2	1.3215	3
3KA11	MMTA - Infectious - Low	Late - Community	0	0.5861	2
3KA21	MMTA - Infectious - Low	Late - Community	1	0.6428	2
3KA31	MMTA - Infectious - Low	Late - Community	2	0.7793	2
4KA11	MMTA - Infectious - Low	Late - Institutional	0	1.0579	3
4KA21	MMTA - Infectious - Low	Late - Institutional	1	1.1146	3
4KA31	MMTA - Infectious - Low	Late - Institutional	2	1.2510	3
1KB11	MMTA - Infectious - Medium	Early - Community	0	1.0114	2
1KB21	MMTA - Infectious - Medium	Early - Community	1	1.0681	2
1KB31	MMTA - Infectious - Medium	Early - Community	2	1.2046	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	1.2178	3
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	1.2746	3
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	1.4110	3
3KB11	MMTA - Infectious - Medium	Late - Community	0	0.6756	2
3KB21	MMTA - Infectious - Medium	Late - Community	1	0.7323	2
3KB31	MMTA - Infectious - Medium	Late - Community	2	0.8688	2
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	1.1474	3
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	1.2041	3
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	1.3405	3
1AC11	MMTA - Other - High	Early - Community	0	1.1089	4
1AC21	MMTA - Other - High	Early - Community	1	1.1657	3
1AC31	MMTA - Other - High	Early - Community	2	1.3021	3
2AC11	MMTA - Other - High	Early - Institutional	0	1.3154	4
2AC21	MMTA - Other - High	Early - Institutional	1	1.3721	4
2AC31	MMTA - Other - High	Early - Institutional	2	1.5086	4
3AC11	MMTA - Other - High	Late - Community	0	0.7732	2
3AC21	MMTA - Other - High	Late - Community	1	0.8299	2
3AC31	MMTA - Other - High	Late - Community	2	0.9663	2
4AC11	MMTA - Other - High	Late - Institutional	0	1.2449	3
4AC21	MMTA - Other - High	Late - Institutional	1	1.3016	3
4AC31	MMTA - Other - High	Late - Institutional	2	1.4381	3
1AA11	MMTA - Other - Low	Early - Community	0	0.9207	3
1AA21	MMTA - Other - Low	Early - Community	1	0.9774	3
1AA31	MMTA - Other - Low	Early - Community	2	1.1139	3
2AA11	MMTA - Other - Low	Early - Institutional	0	1.1272	3
2AA21	MMTA - Other - Low	Early - Institutional	1	1.1839	3
2AA31	MMTA - Other - Low	Early - Institutional	2	1.3203	3
3AA11	MMTA - Other - Low	Late - Community	0	0.5849	2
3AA21	MMTA - Other - Low	Late - Community	1	0.6417	2
3AA31	MMTA - Other - Low	Late - Community	2	0.7781	2
4AA11	MMTA - Other - Low	Late - Institutional	0	1.0567	3
4AA21	MMTA - Other - Low	Late - Institutional	1	1.1134	3
4AA31	MMTA - Other - Low	Late - Institutional	2	1.2499	3
1AB11	MMTA - Other - Medium	Early - Community	0	1.0098	4
1AB21	MMTA - Other - Medium	Early - Community	1	1.0665	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1AB31	MMTA - Other - Medium	Early - Community	2	1.2030	4
2AB11	MMTA - Other - Medium	Early - Institutional	0	1.2162	4
2AB21	MMTA - Other - Medium	Early - Institutional	1	1.2730	4
2AB31	MMTA - Other - Medium	Early - Institutional	2	1.4094	4
3AB11	MMTA - Other - Medium	Late - Community	0	0.6740	2
3AB21	MMTA - Other - Medium	Late - Community	1	0.7308	2
3AB31	MMTA - Other - Medium	Late - Community	2	0.8672	2
4AB11	MMTA - Other - Medium	Late - Institutional	0	1.1458	3
4AB21	MMTA - Other - Medium	Late - Institutional	1	1.2025	3
4AB31	MMTA - Other - Medium	Late - Institutional	2	1.3390	3
1LC11	MMTA - Respiratory - High	Early - Community	0	1.1220	3
1LC21	MMTA - Respiratory - High	Early - Community	1	1.1787	3
1LC31	MMTA - Respiratory - High	Early - Community	2	1.3152	3
2LC11	MMTA - Respiratory - High	Early - Institutional	0	1.3284	4
2LC21	MMTA - Respiratory - High	Early - Institutional	1	1.3852	4
2LC31	MMTA - Respiratory - High	Early - Institutional	2	1.5216	4
3LC11	MMTA - Respiratory - High	Late - Community	0	0.7862	2
3LC21	MMTA - Respiratory - High	Late - Community	1	0.8429	2
3LC31	MMTA - Respiratory - High	Late - Community	2	0.9794	2
4LC11	MMTA - Respiratory - High	Late - Institutional	0	1.2580	3
4LC21	MMTA - Respiratory - High	Late - Institutional	1	1.3147	3
4LC31	MMTA - Respiratory - High	Late - Institutional	2	1.4512	3
1LA11	MMTA - Respiratory - Low	Early - Community	0	0.9125	3
1LA21	MMTA - Respiratory - Low	Early - Community	1	0.9692	3
1LA31	MMTA - Respiratory - Low	Early - Community	2	1.1057	3
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	1.1189	3
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	1.1756	3
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	1.3121	4
3LA11	MMTA - Respiratory - Low	Late - Community	0	0.5767	2
3LA21	MMTA - Respiratory - Low	Late - Community	1	0.6334	2
3LA31	MMTA - Respiratory - Low	Late - Community	2	0.7699	2
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	1.0484	3
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	1.1051	3
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	1.2416	3
1LB11	MMTA - Respiratory - Medium	Early - Community	0	1.0147	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1LB21	MMTA - Respiratory - Medium	Early - Community	1	1.0714	3
1LB31	MMTA - Respiratory - Medium	Early - Community	2	1.2079	3
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	1.2211	4
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	1.2779	4
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	1.4143	4
3LB11	MMTA - Respiratory - Medium	Late - Community	0	0.6789	2
3LB21	MMTA - Respiratory - Medium	Late - Community	1	0.7356	2
3LB31	MMTA - Respiratory - Medium	Late - Community	2	0.8721	2
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	1.1507	3
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	1.2074	3
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	1.3439	3
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	1.1541	3
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	1.2108	3
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	1.3473	2
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	1.3605	4
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	1.4172	4
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	1.5537	4
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	0.8183	2
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	0.8750	2
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	1.0115	2
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	1.2900	3
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	1.3467	3
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	1.4832	4
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	0.9133	3
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	0.9700	2
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	1.1065	2
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	1.1197	3
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	1.1764	3
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	1.3129	3
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	0.5775	2
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	0.6342	2
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	0.7707	2
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	1.0492	3
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	1.1059	3
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	1.2424	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	1.0167	3
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	1.0735	3
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	1.2099	3
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	1.2232	3
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	1.2799	4
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	1.4164	4
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	0.6809	2
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	0.7377	2
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	0.8741	2
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	1.1527	3
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	1.2094	3
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	1.3459	4
1EC11	MS Rehab - High	Early - Community	0	1.1667	5
1EC21	MS Rehab - High	Early - Community	1	1.2234	4
1EC31	MS Rehab - High	Early - Community	2	1.3599	4
2EC11	MS Rehab - High	Early - Institutional	0	1.3731	5
2EC21	MS Rehab - High	Early - Institutional	1	1.4299	5
2EC31	MS Rehab - High	Early - Institutional	2	1.5663	5
3EC11	MS Rehab - High	Late - Community	0	0.8309	2
3EC21	MS Rehab - High	Late - Community	1	0.8876	2
3EC31	MS Rehab - High	Late - Community	2	1.0241	3
4EC11	MS Rehab - High	Late - Institutional	0	1.3027	4
4EC21	MS Rehab - High	Late - Institutional	1	1.3594	4
4EC31	MS Rehab - High	Late - Institutional	2	1.4959	4
1EA11	MS Rehab - Low	Early - Community	0	0.9457	4
1EA21	MS Rehab - Low	Early - Community	1	1.0024	4
1EA31	MS Rehab - Low	Early - Community	2	1.1389	4
2EA11	MS Rehab - Low	Early - Institutional	0	1.1521	4
2EA21	MS Rehab - Low	Early - Institutional	1	1.2088	5
2EA31	MS Rehab - Low	Early - Institutional	2	1.3453	5
3EA11	MS Rehab - Low	Late - Community	0	0.6099	2
3EA21	MS Rehab - Low	Late - Community	1	0.6666	2
3EA31	MS Rehab - Low	Late - Community	2	0.8031	2
4EA11	MS Rehab - Low	Late - Institutional	0	1.0816	4
4EA21	MS Rehab - Low	Late - Institutional	1	1.1383	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4EA31	MS Rehab - Low	Late - Institutional	2	1.2748	4
1EB11	MS Rehab - Medium	Early - Community	0	1.0327	5
1EB21	MS Rehab - Medium	Early - Community	1	1.0895	4
1EB31	MS Rehab - Medium	Early - Community	2	1.2259	4
2EB11	MS Rehab - Medium	Early - Institutional	0	1.2392	5
2EB21	MS Rehab - Medium	Early - Institutional	1	1.2959	5
2EB31	MS Rehab - Medium	Early - Institutional	2	1.4324	5
3EB11	MS Rehab - Medium	Late - Community	0	0.6970	2
3EB21	MS Rehab - Medium	Late - Community	1	0.7537	2
3EB31	MS Rehab - Medium	Late - Community	2	0.8902	2
4EB11	MS Rehab - Medium	Late - Institutional	0	1.1687	4
4EB21	MS Rehab - Medium	Late - Institutional	1	1.2254	4
4EB31	MS Rehab - Medium	Late - Institutional	2	1.3619	4
1BC11	Neuro - High	Early - Community	0	1.2820	4
1BC21	Neuro - High	Early - Community	1	1.3387	4
1BC31	Neuro - High	Early - Community	2	1.4752	4
2BC11	Neuro - High	Early - Institutional	0	1.4884	5
2BC21	Neuro - High	Early - Institutional	1	1.5451	4
2BC31	Neuro - High	Early - Institutional	2	1.6816	4
3BC11	Neuro - High	Late - Community	0	0.9462	2
3BC21	Neuro - High	Late - Community	1	1.0029	3
3BC31	Neuro - High	Late - Community	2	1.1394	3
4BC11	Neuro - High	Late - Institutional	0	1.4179	4
4BC21	Neuro - High	Late - Institutional	1	1.4746	4
4BC31	Neuro - High	Late - Institutional	2	1.6111	4
1BA11	Neuro - Low	Early - Community	0	1.0363	4
1BA21	Neuro - Low	Early - Community	1	1.0931	4
1BA31	Neuro - Low	Early - Community	2	1.2295	4
2BA11	Neuro - Low	Early - Institutional	0	1.2428	4
2BA21	Neuro - Low	Early - Institutional	1	1.2995	4
2BA31	Neuro - Low	Early - Institutional	2	1.4360	4
3BA11	Neuro - Low	Late - Community	0	0.7005	2
3BA21	Neuro - Low	Late - Community	1	0.7573	2
3BA31	Neuro - Low	Late - Community	2	0.8937	2
4BA11	Neuro - Low	Late - Institutional	0	1.1723	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4BA21	Neuro - Low	Late - Institutional	1	1.2290	3
4BA31	Neuro - Low	Late - Institutional	2	1.3655	3
1BB11	Neuro - Medium	Early - Community	0	1.1425	4
1BB21	Neuro - Medium	Early - Community	1	1.1992	4
1BB31	Neuro - Medium	Early - Community	2	1.3357	4
2BB11	Neuro - Medium	Early - Institutional	0	1.3489	5
2BB21	Neuro - Medium	Early - Institutional	1	1.4057	5
2BB31	Neuro - Medium	Early - Institutional	2	1.5421	5
3BB11	Neuro - Medium	Late - Community	0	0.8067	2
3BB21	Neuro - Medium	Late - Community	1	0.8634	2
3BB31	Neuro - Medium	Late - Community	2	0.9999	2
4BB11	Neuro - Medium	Late - Institutional	0	1.2785	4
4BB21	Neuro - Medium	Late - Institutional	1	1.3352	4
4BB31	Neuro - Medium	Late - Institutional	2	1.4716	4
1CC11	Wound - High	Early - Community	0	1.5596	4
1CC21	Wound - High	Early - Community	1	1.6163	4
1CC31	Wound - High	Early - Community	2	1.7528	4
2CC11	Wound - High	Early - Institutional	0	1.7660	5
2CC21	Wound - High	Early - Institutional	1	1.8228	4
2CC31	Wound - High	Early - Institutional	2	1.9592	4
3CC11	Wound - High	Late - Community	0	1.2238	3
3CC21	Wound - High	Late - Community	1	1.2805	3
3CC31	Wound - High	Late - Community	2	1.4170	3
4CC11	Wound - High	Late - Institutional	0	1.6956	4
4CC21	Wound - High	Late - Institutional	1	1.7523	4
4CC31	Wound - High	Late - Institutional	2	1.8887	4
1CA11	Wound - Low	Early - Community	0	1.3450	4
1CA21	Wound - Low	Early - Community	1	1.4017	4
1CA31	Wound - Low	Early - Community	2	1.5382	4
2CA11	Wound - Low	Early - Institutional	0	1.5514	4
2CA21	Wound - Low	Early - Institutional	1	1.6082	4
2CA31	Wound - Low	Early - Institutional	2	1.7446	4
3CA11	Wound - Low	Late - Community	0	1.0092	3
3CA21	Wound - Low	Late - Community	1	1.0659	3
3CA31	Wound - Low	Late - Community	2	1.2024	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4CA11	Wound - Low	Late - Institutional	0	1.4810	4
4CA21	Wound - Low	Late - Institutional	1	1.5377	4
4CA31	Wound - Low	Late - Institutional	2	1.6742	4
1CB11	Wound - Medium	Early - Community	0	1.4260	4
1CB21	Wound - Medium	Early - Community	1	1.4828	4
1CB31	Wound - Medium	Early - Community	2	1.6192	4
2CB11	Wound - Medium	Early - Institutional	0	1.6325	4
2CB21	Wound - Medium	Early - Institutional	1	1.6892	5
2CB31	Wound - Medium	Early - Institutional	2	1.8257	4
3CB11	Wound - Medium	Late - Community	0	1.0903	3
3CB21	Wound - Medium	Late - Community	1	1.1470	3
3CB31	Wound - Medium	Late - Community	2	1.2835	3
4CB11	Wound - Medium	Late - Institutional	0	1.5620	4
4CB21	Wound - Medium	Late - Institutional	1	1.6187	4
4CB31	Wound - Medium	Late - Institutional	2	1.7552	4

Source: CY 2024 Home Health Claims Data. Periods that end in CY 2024 accessed on the CCW March 13, 2025.

period payment rate by a case-mix budget neutrality factor. Typically, the case-mix weight recalibration neutrality factor is also calculated using the most recent, complete home health claims data available. For CY 2026, we would continue the practice of using the most recent complete home health claims data at the time of rulemaking, which is CY 2024 data. The case-mix budget neutrality factor is calculated as the ratio of 30-day base payment rates such that total payments when the CY 2026 PDGM case-mix weights (developed using CY 2024 home health claims data) are applied to CY 2024 utilization (claims) data are equal to total payments when CY 2025 PDGM case-mix weights (developed using CY 2023 home health claims data) are applied to CY 2024 utilization data. This produces a case-mix budget neutrality factor for CY 2026 of 1.0051.

We invite public comments on the CY 2026 proposed case-mix weights and proposed case-mix weight budget neutrality factor.

E. Proposed CY 2026 Home Health Payment Rate Updates

1. Proposed CY 2026 Home Health Market Basket Update for HHAs

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for home health be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. In the CY 2024 HH PPS final rule (88 FR 77726), we finalized a rebasing of the home health market basket to reflect 2021 cost report data. We also finalized a policy for CY 2024 and subsequent years that the labor-related share will be 74.9 percent, and the non-labor-related share will be 25.1 percent. A detailed description of how we rebased the home health market basket and labor-related share is available in the CY 2024 HH PPS final rule (88 FR 77726 through 77742).

In the CY 2015 HH PPS final rule (79 FR 38384), we finalized our methodology for calculating and applying the multifactor productivity adjustment. As we explained in that rule, section 1895(b)(3)(B)(vi) of the Act, requires that, in CY 2015 (and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015)), the market basket percentage under the HH PPS as described in section 1895(b)(3)(B) of the Act be annually adjusted by changes in

economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term “multifactor productivity” with “total factor productivity” (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as “private nonfarm business total factor productivity”. We refer readers to <https://www.bls.gov> for the BLS historical published TFP data. A complete description of IHS Global Inc.’s (IGI) TFP projection methodology is available on the CMS website at <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information>.

The proposed home health update percentage for CY 2026 is based on the estimated home health market basket percentage increase, specified at section 1895(b)(3)(B)(iii) of the Act, of 3.2 percent (based on IHS Global Inc.’s first quarter 2025 forecast with historical data through fourth quarter 2024). The estimated CY 2026 proposed home health market basket percentage increase of 3.2 percent would then be reduced by a productivity adjustment, in accordance with section 1895(b)(3)(B)(vi) of the Act. Based on IGI’s first quarter 2025 forecast, the proposed productivity adjustment is currently estimated to be 0.8 percentage point for CY 2026. Therefore, the proposed productivity-adjusted CY 2026 home health market basket update is 2.4 percent (3.2 percent market basket percentage increase, reduced by a 0.8 percentage point productivity adjustment). Furthermore, we are proposing that if more recent data become available (for example, a more recent estimate of the market basket percentage increase and/or productivity

adjustment), we would use such data, if appropriate, to determine the CY 2026 market basket percentage increase and productivity adjustment in the final rule.

Section 1895(b)(3)(B)(v) of the Act requires that the home health percentage update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2026, the proposed home health payment update percentage is 0.4 percent (2.4 percent minus 2 percentage points).

We invite public comments on the proposed CY 2026 home health market basket percentage increase and productivity adjustment.

2. Proposed CY 2026 Home Health Wage Index

a. Background

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to home health payments. We are proposing to continue this practice for CY 2026, as it is our belief that, in the absence of home health-specific wage data that accounts for area differences, using inpatient hospital wage data, including any changes made by the Office of Management and Budget (OMB) to Metropolitan Statistical Area (MSA) definitions, is appropriate and reasonable for the HH PPS.

In general, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded the August 15, 2017, OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018, OMB Bulletin No. 18–03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A

copy of OMB Bulletin No. 18–04 may be obtained at <https://www.bls.gov/bls/omb-bulletin-18-04-revised-delineations-of-metropolitan-statistical-areas.pdf>. In the CY 2021 HH PPS final rule (85 FR 70298), we finalized our proposal to adopt the revised OMB delineations with a 5 percent cap on wage index decreases in CY 2021.

On July 21, 2023, OMB issued Bulletin No. 23–01, which updates and supersedes OMB Bulletin No. 20–01, issued on March 6, 2020. OMB Bulletin No. 23–01 establishes revised delineations for the MSAs, Micropolitan Statistical Areas, Combined Statistical Areas, and Metropolitan Divisions, collectively referred to as Core Based Statistical Areas (CBSAs). According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (CBSAs) (the “2020 Standards”), which appeared in the **Federal Register** (86 FR 37770 through 37778) on July 16, 2021, and application of those standards to Census Bureau population and journey-to-work data (for example, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). A copy of OMB Bulletin No. 23–01 is available online at <https://www.bls.gov/bls/omb-bulletin-23-01-revised-delineations-of-metropolitan-statistical-areas.pdf>.

In the CY 2025 HH PPS final rule (89 FR 88354), we finalized our proposal to adopt the revised OMB delineations from OMB Bulletin 23–01 with a 5 percent cap on wage index decreases at the CBSA level as well as at the county level. In that final rule we stated that we believe it is important for the HH PPS wage index to use the latest OMB delineations available in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We also stated that we believe using the most current OMB delineations will increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels.

b. Five Percent Cap on Wage Index Decreases

In the CY 2023 HH PPS final rule (87 FR 66851 through 66853), we finalized a policy that the CY HH PPS wage index will include a permanent 5 percent cap on wage index decreases for CY 2023 and each subsequent year. Specifically, we finalized, for CY 2023 and subsequent years, the application of a permanent 5 percent cap on any decrease to a geographic area’s wage index from its wage index in the prior year, regardless of the circumstances

causing the decline. That is, we finalized a policy requiring that a geographic area’s wage index for CY 2023 will not be less than 95 percent of its final wage index for CY 2022, regardless of whether the geographic area is part of an updated CBSA, and that for subsequent years, a geographic area’s wage index will not be less than 95 percent of its wage index calculated in the prior CY.

Previously this methodology was applied to all counties that make up a CBSA or statewide rural area. However, in the CY 2025 HH PPS final rule (89 FR 88418 through 88421), because of the adoption of the revised OMB delineations from OMB Bulletin 23–01, we finalized a policy applying this methodology to individual counties. Specifically, we finalized a policy applying the 5 percent cap to counties that moved from a CBSA or statewide rural area with a higher wage index value into a new CBSA or rural area with a lower wage index value, so that the county’s CY 2025 wage index would not be less than 95 percent of the county’s CY 2024 wage index value under the old delineation despite moving into a new delineation with a lower wage index.

Due to the way that we proposed calculating the 5 percent cap for counties that experienced an OMB designation change, some CBSAs and statewide rural areas could have had more than one wage index value. Specifically, some counties that changed OMB designations had a wage index value that was different than the wage index value assigned to the other constituent counties that made up that CBSA or statewide rural area that they moved into after the application of the 5 percent cap. However, for home health claims processing, each CBSA or statewide rural area can have only one wage index value assigned to that CBSA or statewide rural area. Therefore, we finalized a policy, beginning in CY 2025, that counties that have a different wage index value than the CBSA or rural area into which they are designated after the application of the 5 percent cap will use a wage index transition code. These special codes are five digits in length and begin with “50” and the remaining digits are unique for that code. The 50XXX wage index transition codes are used only in specific counties; counties located in CBSAs and rural areas that do not correspond to a different transition wage index value will still use the CBSA number.

We also finalized a policy applying the 5 percent cap to these specific counties that correspond to a different

wage index value due to a delineation change until the county’s new wage index is more than 95 percent of the wage index from the previous calendar year. In order to capture the correct wage index value, an HHA will continue to use the assigned 50XXX transition code on home health claims for services in these counties until the county’s wage index value calculated for that calendar year using the new OMB delineations is not less than 95 percent of the county’s capped wage index from the previous calendar year.

For CY 2026, the 5 percent cap on wage index decreases will continue to be calculated at the county level as well as the CBSA and statewide rural area level. While some counties that required a transition code for CY 2025 will continue to use the same transition code for CY 2026, other counties that required a transition code in CY 2025 will no longer require a transition code in CY 2026. In the counties that will no longer require a transition code beginning in CY 2026 wage index, the CY 2026 wage index of the CBSA or rural area that the county was redesignated into has a wage index value higher than 95 percent of the county’s CY 2025 wage index. Therefore, these counties will use the CBSA or rural county code of the area they were redesignated into based on OMB Bulletin No. 23–01.

The complete list of counties and corresponding transition codes can be found as a separate tab in the calendar year’s wage index file located on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health-pps/home-health-pps-wage-index>.

c. Proposed CY 2026 HH PPS Wage index

The appropriate wage index value is applied to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined in section 1861(m) of the Act as the beneficiary’s place of residence). For CY 2026, we are proposing to base the HH PPS wage index on the FY 2026 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022 (FY 2022 cost report data). The proposed CY 2026 HH PPS wage index would not take into account any geographic reclassification of hospitals, including those in accordance with sections 1886(d)(8)(B) or 1886(d)(10) of the Act but would include the 5 percent cap on wage index decreases as discussed previously.

There exist some geographic areas where there are no hospitals, and thus,

no hospital wage data on which to base the calculation of the HH PPS wage index. To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2026 HH PPS wage index, we are proposing to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals.

For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the State as a reasonable proxy for the wage index for that CBSA. For CY 2026, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980). Using the average wage index of all urban areas in Georgia as a proxy, we are proposing the CY 2026 wage index value for Hinesville, GA, would be 0.8800.

For rural areas that do not have inpatient hospitals, we use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. The term “contiguous” means sharing a border (72 FR 49859). In the CY 2025 HH PPS final rule (89 FR 88422), we finalized a policy that rural North Dakota would become a rural area without a hospital from which hospital wage data can be derived. Therefore, in order to calculate the wage index for rural area 99935, North Dakota, we finalized using as a proxy, the average pre-floor, pre-reclassified hospital wage data from the contiguous CBSAs: CBSA 13900-Bismark, ND, CBSA 22020-Fargo, ND-MN, CBSA 24220-Grand Forks, ND-MN, and CBSA 33500, Minot, ND. Using this methodology, we are proposing that the CY 2026 HH PPS wage index for rural North Dakota would be 0.8346.

Previously, the only rural area without a hospital from which hospital wage data could be derived was rural Puerto Rico. However, for rural Puerto Rico, we did not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the proximity of almost all of Puerto Rico’s various urban and non-urban areas to one another, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we used the most recent wage index previously available for that area, which was 0.4047. Beginning in CY 2025, due to the adoption of the revised OMB delineations, there is now a hospital in rural Puerto Rico from which hospital wage data can be derived. Therefore, we finalized a policy that the wage index for rural Puerto Rico would

now be based on the hospital wage data for the area instead of the previously available wage index of 0.4047. The CY 2025 final unadjusted wage index value for rural Puerto Rico was 0.2510. However, because 0.2510 is more than a 5 percent decline in the area’s CY 2024 wage index, the 5 percent cap was applied and the final CY 2025 5 percent cap adjusted wage index for rural Puerto Rico was set equal to 95 percent of the CY 2024 wage index, which resulted in a final wage index value of 0.3845.

The unadjusted CY 2026 proposed wage index for rural Puerto Rico is 0.2452. However, because 0.2452 is more than a 5 percent decline in the CY 2025 wage index, we are proposing that the CY 2026 5 percent cap adjusted wage index for rural Puerto Rico be set equal to 95 percent of the CY 2025 wage index, which would result in a proposed wage index value of 0.3653.

Additionally, due to the adoption of the revised OMB delineations in the CY 2025 HH PPS final rule, Delaware, which was previously an all-urban state, now has one rural area with a hospital from which hospital wage data can be derived. As such, we are proposing that the CY 2026 wage index for rural Delaware would be 1.0133.

Finally, the Northern Mariana Islands and American Samoa are rural areas with no hospital data from which a wage index can be calculated. Consistent with our established methodology, we compute an appropriate wage index for rural areas with no hospital using the average wage index values from contiguous CBSAs, to represent a reasonable proxy. Therefore, we are proposing that HHAs that provide services in the Northern Mariana Islands and American Samoa would use CBSA 99965 (Guam) and receive the wage index assigned to CBSA 99965 (Guam) of 0.9611. While we appreciate that the islands of the Pacific Rim are not actually contiguous, we believe that same principle applies here, and that Guam is a reasonable proxy for American Samoa and the Northern Mariana Islands. We believe that CBSA 99965 (Guam) represents a reasonable proxy because the islands are located within the Pacific Rim and share a common status as United States Territories.

The proposed HH PPS wage index file applicable for CY 2026 (January 1, 2026, through December 31, 2026) is available on the CMS website at <https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center>.

3. Proposed CY 2026 Home Health Payment Update

a. Background

The HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000, final rule (65 FR 41128), the base unit of payment under the HH PPS was a national, standardized 60-day episode payment rate. As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56406), and as described in the CY 2020 HH PPS final rule with comment period (84 FR 60478), the unit of home health payment changed from a 60-day episode to a 30-day period effective for those 30-day periods beginning on or after January 1, 2020.

As set forth in § 484.220, we adjust the national, standardized prospective payment rates by a case-mix relative weight and a wage index value based on the site of service for the beneficiary. To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. In the CY 2024 HH PPS final rule (88 FR 77676), we finalized the rebasing of the home health market basket to reflect 2021 Medicare cost report data. We also finalized a policy that, for CY 2024 and subsequent years, the labor-related share will be 74.9 percent, and the non-labor-related share will be 25.1 percent. The following are the steps we take to compute the case-mix and wage-adjusted 30-day period payment amount for CY 2026:

- Multiply the national, standardized 30-day period rate by the patient’s applicable case-mix weight.
- Divide the case-mix adjusted amount into a labor (74.9 percent) and a non-labor portion (25.1 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 30-day period payment amount, subject to any additional applicable adjustments.

We provide annual updates of the HH PPS rate in accordance with section 1895(b)(3)(B) of the Act. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with section 1895(b)(3)(B)(v) of the Act and § 484.225(i), for an HHA that does not submit home health quality data, as specified by the Secretary, the unadjusted national prospective 30-day period rate is equal to the rate for the previous calendar year increased by the applicable home health payment update

percentage, minus two percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will not be considered in computing the prospective payment amount for a subsequent calendar year.

The final claim that the HHA submits for payment determines the total payment amount for the period and whether we make an applicable adjustment to the 30-day case-mix and wage-adjusted payment amount. The end date of the 30-day period, as reported on the claim, determines which calendar year rates Medicare would use to pay the claim.

We may adjust a 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect the following:

- A LUPA is provided on a per-visit basis as set forth in §§ 484.205(d)(1) and 484.230.
- A partial payment adjustment as set forth in §§ 484.205(d)(2) and 484.235.
- An outlier payment as set forth in §§ 484.205(d)(3) and 484.240.

b. Proposed CY 2026 National, Standardized 30-Day Period Payment Amount

Section 1895(b)(3)(A)(i) of the Act requires that the standard prospective payment rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget-neutral manner. To determine the CY 2026 national, standardized 30-day period payment rate, we would continue our practice of using the most recent,

complete utilization data at the time of rulemaking; that is, we are using CY 2024 claims data for CY 2026 payment rate updates. We apply a permanent adjustment factor, a case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor, the home health payment update percentage, and a temporary adjustment factor to update the CY 2026 payment rate. As discussed in section II.C.1. of this proposed rule, we are proposing the implementation of a permanent adjustment of – 4.059 percent to ensure that estimated aggregate expenditures under the PDGM are equal to the estimated aggregate expenditures that otherwise would have been under the 153-group payment system as required by law. The proposed permanent adjustment factor is 0.95941. As discussed previously, to ensure the changes to the PDGM case-mix weights are implemented in a budget neutral manner, we apply a case-mix weight budget neutrality factor to the CY 2026 national, standardized 30-day period payment rate. The proposed case-mix weight budget neutrality factor for CY 2026 is 1.0051.

Additionally, we apply a wage index budget neutrality factor to ensure that wage index updates and revisions are implemented in a budget neutral manner. To calculate the wage index budget neutrality factor, we first determine the payment rate needed for non-LUPA 30-day periods using the CY 2026 wage index (with the 5 percent cap) so those total payments are equivalent to the total payments for non-LUPA 30-day periods using the CY 2025 wage index (with the 5 percent cap) and the CY 2025 national

standardized 30-day period payment rate adjusted by the case-mix weights recalibration neutrality factor. Then, by dividing the payment rate for non-LUPA 30-day periods using the CY 2026 wage index with the 5 percent cap on wage index decreases) by the payment rate for non-LUPA 30-day periods using the CY 2025 wage index (with the 5 percent cap on wage index decreases), we obtain a wage index budget neutrality factor of 1.0019. We then apply the wage index budget neutrality factor of 1.0019 to the 30-day period payment rate.

Next, we update the 30-day period payment rate by the proposed CY 2026 home health payment update percentage of 2.4 percent. As discussed in section II.C.1. of this proposed rule, we are also proposing the implementation of a temporary 5.0 percent reduction to the CY 2026 base payment rate. The proposed temporary adjustment factor is 0.95000. Per section 1895(b)(3)(D)(iii) of the Act a temporary adjustment is to be applied for the applicable year and not included when computing a payment rate for a subsequent year. In other words, the temporary adjustment factor for CY 2026 should not be included in the starting payment rate for CY 2027. Therefore, we have calculated the CY 2026 national, standardized 30-day period payment with and without the temporary adjustment factor. The CY 2026 national standardized 30-day period payment rate without a temporary adjustment is only for illustrative purposes. The actual CY 2026 national standardized 30-day period payment rate includes the proposed temporary adjustment and is calculated in table 26.

TABLE 26: CY 2026 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2025 National Standardized 30-Day Period Payment	Permanent Adjustment Factor	CY 2026 Case-Mix Weights Recalibration Neutrality Factor	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor	CY 2026 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)	Temporary Adjustment Factor	CY 2026 National, Standardized 30-Day Period Payment (With Temporary Adjustment)
\$2,057.35	0.95941	1.0051	1.0019	1.024	\$2,035.38	0.95000	\$1,933.61

The CY 2026 national standardized 30-day period payment rate for an HHA that does not submit the required

quality data would be updated by 0.4 percent (the proposed CY 2026 home health payment update percentage of 2.4

percent minus 2 percentage points) and is shown in table 27.

TABLE 27: CY 2026 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2025 National Standardized 30-Day Period Payment	Permanent Adjustment Factor	CY 2026 Case-Mix Weights Recalibration Neutrality Factor	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor Minus 2 Percentage Points	CY 2026 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)	Temporary Adjustment Factor	CY 2026 National, Standardized 30-Day Period Payment (With Temporary Adjustment)
\$2,057.35	0.95941	1.0051	1.0019	1.004	\$1,995.63	0.95000	\$1,895.85

c. Proposed CY 2026 National Per-Visit Rates for 30-Day Periods of Care

The national per-visit rates are used to pay LUPAs and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or home health discipline. The six home health disciplines are as follows:

- Home health aide (HH aide).
- Medical Social Services (MSS).
- Occupational therapy (OT).
- Physical therapy (PT).
- Skilled nursing (SN).
- Speech-language pathology (SLP).

To calculate the proposed CY 2026 national per-visit rates, we started with the CY 2025 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA 30-day periods of care using the CY 2026 wage index with the 5 percent cap on wage index

decreases and comparing it to simulated total payments for LUPA 30-day periods of care using the CY 2025 wage index with the 5 percent cap. By dividing the total payments for LUPA 30-day periods of care using the CY 2026 wage index by the total payments for LUPA 30-day periods of care using the CY 2025 wage index, we obtained a wage index budget neutrality factor of 1.0004. As a reminder, the wage index budget neutrality factors for the national, standardized 30-day period amount and the national LUPA per-visit rates are not equal because they are calculated differently. The wage index budget neutrality factor for the LUPA per-visit payments is calculated by simulating total payments for LUPA 30-day periods while the 30-day period budget neutrality factor is calculated by simulating payments for non-LUPA 30-day periods.

The LUPA per-visit rates are not calculated using case-mix weights.

Therefore, no case-mix weight budget neutrality factor is needed to ensure budget neutrality for LUPA payments. Additionally, we are not applying the permanent adjustment or the temporary adjustment to the per-visit payment rates but only to the case-mix adjusted 30-day payment rate. Lastly, the per-visit rates for each discipline are updated by the proposed CY 2026 home health payment update percentage of 2.4 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for periods that occur as the only period or initial period in a sequence of adjacent periods. The proposed CY 2026 national per-visit rates for HHAs that submit the required quality data are updated by the proposed CY 2026 home health payment update percentage of 2.4 percent and are shown in table 28.

TABLE 28: CY 2026 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2025 Per-Visit Payment Amount	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor	CY 2026 Per-Visit Payment Amount
Home Health Aide	\$78.20	1.0004	1.024	\$80.11
Medical Social Services	\$276.85	1.0004	1.024	\$283.61
Occupational Therapy	\$190.08	1.0004	1.024	\$194.72
Physical Therapy	\$188.79	1.0004	1.024	\$193.40
Skilled Nursing	\$172.73	1.0004	1.024	\$176.95
Speech-Language Pathology	\$205.22	1.0004	1.024	\$210.23

The CY 2026 per-visit payment rates for HHAs that do not submit the required quality data would be updated

by 0.4 percent, which is the proposed CY 2026 home health payment update percentage of 2.4 percent minus 2

percentage points and are shown in table 29.

TABLE 29: CY 2026 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2025 Per-Visit Payment Amount	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor Minus 2 Percentage Points	CY 2026 Per-Visit Payment Amount
Home Health Aide	\$78.20	1.0004	1.004	\$78.54
Medical Social Services	\$276.85	1.0004	1.004	\$278.07
Occupational Therapy	\$190.08	1.0004	1.004	\$190.92
Physical Therapy	\$188.79	1.0004	1.004	\$189.62
Skilled Nursing	\$172.73	1.0004	1.004	\$173.49
Speech-Language Pathology	\$205.22	1.0004	1.004	\$206.12

We are soliciting comments on the proposed CY 2026 30-day home health payment rates and the per-visit payment rates.

d. LUPA Add-On Factors

Prior to the implementation of the 30-day unit of payment, LUPA episodes were eligible for a LUPA add-on payment if the episode of care was the first or only episode in a sequence of adjacent episodes. As described in the CY 2008 HH PPS final rule, the average visit lengths in these initial LUPAs are 16 to 18 percent higher than the average visit lengths in initial non-LUPA episodes (72 FR 49848). LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences.

In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount, whereby we finalized the approach of multiplying the per-visit payment amount for the first skilled nursing (SN), physical therapy (PT), or speech language pathology (SLP) visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by 1 + the proportional increase in minutes for an initial visit over non-initial visits. Specifically, we updated the analysis using 100 percent of LUPA episodes and a 20 percent sample of non-LUPA first episodes from CY 2012 claims data. At that time, we finalized add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. In the CY 2019 HH PPS final rule with comment period (83 FR 56440), in addition to finalizing a 30-day unit of payment, we finalized our policy of continuing to multiply the per-

visit payment amount for the first SN, PT, or SLP visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor (using the already established LUPA add-on factors of 1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount for 30-day periods of care under the PDGM.

In the CY 2025 HH PPS final rule (89 FR 88426 through 88427), in an effort to enhance the accuracy and relevance of LUPA add-on factors to reflect current healthcare practices and costs, we finalized updates to the LUPA add-on factors for PT, SN, and SLP, which had not been revised since the CY 2014 HH PPS final rule (using CY 2012 claims data). We finalized the proposal to use the same methodology to establish the LUPA add-on amount for CY 2014, using updated claims data.

Specifically, we updated the LUPA add-on factors by using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from CY 2023 claims data (as of September 11, 2024). Our analysis found that the average excess of minutes for the first visit in LUPA periods that were the only period or an initial LUPA in a sequence of adjacent periods are 29.91 minutes for the first visit if SN, 28.08 minutes for the first visit if PT, and 31.57 minutes for the first visit if SLP. The average minutes for all non-first visits in non-LUPA episodes are 41.54 minutes for SN, 45.11 minutes for PT, and 47.15 minutes for SLP. To determine the LUPA add-on factors for each discipline, we calculated the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. We then added one to

these ratios to obtain the final add on factors. Therefore, beginning in CY 2025 the final LUPA add on factors for SN, PT, and SLP are 1.7200 for SN; 1.6225 for PT; and 1.6696 for SLP.

Additionally, as outlined in the CY 2025 HH PPS proposed rule (89 FR 55378), in order to implement Division CC, section 115, of the Consolidation Appropriations Act (CAA), 2021, CMS finalized changes to the regulations at § 484.55(a)(2) and (b)(3) that allowed occupational therapists to conduct initial and comprehensive assessments for all Medicare beneficiaries under the home health benefit when the plan of care does not initially include skilled nursing care, but included OT, as well as either PT or SLP (86 FR 62351). This change necessitated the establishment of a LUPA add-on factor for calculating the LUPA add-on payment amount for the first skilled OT visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care. However, at the time of the implementation, we stated in the CY 2022 HH PPS final rule (86 FR 62289), there was not sufficient data regarding the average excess minutes for the first visit in LUPA periods when the initial and comprehensive assessments are conducted by occupational therapists. Therefore, we finalized a policy using the PT LUPA add-on factor as a proxy. We also stated in the CY 2022 final rule that we will use the PT LUPA add-on factor as a proxy until we have CY 2022 data to establish a more accurate OT add-on factor for the LUPA add-on payment amounts (86 FR 62289). Ultimately, we refrained from using CY 2022 data (and instead utilized the PT LUPA add-on factor as a proxy for the OT LUPA add-on factor), as we marked the first year that occupational

therapists were permitted to conduct the initial assessment. We wanted to extend our analysis to ensure we had sufficient data to reflect OT time spent conducting initial assessments to establish a discrete OT LUPA add-on factor (86 FR 62240).

In the CY 2025 HH PPS final rule (89 FR 88427), we finalized a proposal to discontinue use of the PT LUPA add-on factor as a proxy and established a definitive LUPA add-on factor for occupational therapy. We used the same methodology used to establish the LUPA add-on amount for CY 2014, as described previously for the SN, PT, and SLP add-on factors. Specifically, we updated the analysis using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from CY 2023 claims data. Using updated analysis (as of September 11, 2024), we found that the average excess of minutes for the first OT visit in LUPA periods that were the only period or an initial LUPA in a sequence of adjacent periods is 33.28 minutes for the first visit. The average number of minutes for all non-first visits in non-LUPA periods is 45.98 minutes for OT. To determine the LUPA add-on factor for OT to account for the excess minutes during the first visit in a LUPA period, we finalized calculating the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. We then added one to this ratio to obtain the final add on factor of 1.7238 for OT. Therefore, the OT LUPA factor of 1.7238 is used when occupational therapy is the first skilled visit in a LUPA period that occurs as the only period or an initial period in a sequence of adjacent periods.

4. Payments for High-Cost Outliers Under the HH PPS

a. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS and the previous unit of payment (that is, 60-day episodes), outlier payments were made for 60-day episodes whose estimated costs exceed a threshold amount for each HHRG. The episode's estimated cost was established as the sum of the national wage-adjusted per-visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or PEP adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL)

amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the home health FDL ratio by a case's wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined as a proportion of the wage-adjusted estimated cost that surpasses the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act to require that the Secretary reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act and revised the language to state that the total amount of the additional payments or payment adjustments for outlier episodes could not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act, which capped outlier payments as a percent of total payments for each HHA for each year at 10 percent.

As such, beginning in CY 2011, we reduced payment rates by 5 percent and targeted up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we targeted up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10-percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the

number of visits during an episode of care in order to surpass the outlier threshold and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76702), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim would receive an outlier payment and the amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes (81 FR 76725). Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

In the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, the per unit rates used to estimate an episode's cost were updated by the home health update percentage each year, meaning we would start with the national per visit amounts for the same calendar year when calculating the cost-per-unit used to determine the cost of an episode of care (81 FR 76727). We would continue to monitor the visit length by discipline as more recent data becomes available and may propose updating the rates as needed in the future.

In the CY 2019 HH PPS final rule with comment period (83 FR 56521), we finalized a policy to maintain the current methodology for payment of high-cost outliers upon implementation of PDGM beginning in CY 2020 and calculated payment for high-cost outliers based upon 30-day period of care. Upon implementation of the PDGM and 30-day unit of payment, we finalized the FDL ratio of 0.56 for 30-

day periods of care in CY 2020. In the CY 2025 HH PPS final rule (89 FR 88354), using CY 2023 claims data (as of July 11, 2024), we finalized the FDL ratio of 0.35 for CY 2025.

b. Proposed FDL Ratio for CY 2026

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of periods that can receive outlier payments but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier periods. Alternatively, a lower FDL ratio means that more periods can qualify for outlier payments, but outlier payments per period must be lower.

The FDL ratio and the loss-sharing ratio are selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio, which we believe preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs that exceed the outlier threshold amount.

Using CY 2024 claims data (as of March 13, 2025) and given the statutory requirement that total outlier payments do not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we are proposing an FDL ratio of 0.46 for CY 2026. CMS would update the FDL, if needed, in the final rule once we have more complete CY 2024 claims data.

F. Proposed Regulation Change to Face-to-Face Encounter

As a condition for payment, section 6407(a) of the Affordable Care Act (Pub. L. 111–148, March 23, 2010) requires that prior to certifying a patient's eligibility for the home health benefit, the physician must document that the physician himself or herself or a non-physician practitioner (NPP) has had a face-to-face encounter with the patient. In the Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices final rule (75 FR 70427) (hereinafter referred to as the CY 2011 HH PPS final rule), we established that the certifying physician must document the face-to-face encounter regardless of whether the physician himself or herself or one of the permitted NPPs performed the face-to-face encounter. Sections 6407(a)(1)(B) and 6407(a)(2)(B) of the Affordable Care

Act further describes NPPs who may perform this face-to-face patient encounter.

In the Medicare Program, Home Health Prospective Payment System Rate Update for Calendar Year 2012 final rule (hereinafter referred to as the CY 2012 HH PPS final rule), we stated that the Medicare home health benefit relies on the patient's physician to determine eligibility for home health services (76 FR 68596), noting that this type of physician involvement is critical from both a quality of care and program integrity perspective. Prior to enactment of section 6407(a) of the Affordable Care Act regarding the home health face-to-face encounter provision, the patient's physician often relied on information provided by an HHA when making decisions about patient care. In the CY 2012 HH PPS final rule (76 FR 68597), we stated that, in addition to the certifying physician and allowed NPPs, the physician who cared for the patient in an acute or post-acute care facility, and who had privileges in such facility, could also perform the face-to-face encounter and inform the certifying physician, who would document the encounter as part of the certification of eligibility, and that encounter supported the patient's homebound status and need for skilled services. During the CY 2012 HH PPS rulemaking comment period, stakeholders requested that CMS allow any physician to complete the face-to-face encounter, rather than limiting it to the certifying physician or allowed NPP; however, CMS referred commenters to the CY 2011 HH PPS final rule where we stated we did not believe that we had the statutory authority to allow for this additional flexibility (76 FR 68596). The Affordable Care Act established the requirement for a physician face-to-face encounter prior to certifying a patient's eligibility for home health services, along with other program integrity provisions, to address concerns surrounding ineligible patients receiving home health services and concerns that physicians who had no firsthand knowledge of the patient's clinical condition were certifying the patient's eligibility for home health. In the CY 2011 HH PPS final rule, we described research that showed fewer re-hospitalizations when the home health patient had a recent encounter with the physician responsible for the home health care plan. As such, 42 CFR 424.22(a)(1)(v)(A) requires that a face-to-face encounter be performed by the certifying physician; the certifying allowed practitioner (for example, nurse practitioner, clinical nurse specialist, physician assistant); or a certified nurse

midwife. Additionally, 42 CFR 424.22(a)(1)(v)(C) requires that a face-to-face encounter be performed by the certifying physician or allowed practitioner unless the encounter is performed by a certified nurse midwife or a physician, physician assistant, nurse practitioner, or clinical nurse specialist with privileges who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health and who is different from the certifying practitioner.

Section 3708 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116–136, March 27, 2020) amended sections 1814(a) and 1835(a) of the Act to allow nurse practitioners (NPs), clinical nurse specialists (CNSs), and physician assistants (PAs) (as those terms are defined in section 1861(aa) of the Act), to order and certify patients for eligibility under the Medicare home health benefit and establish a plan of care. Since its implementation in the March 31, 2020 COVID–19 interim final rule with comment period (85 FR 27550), CMS has received requests from stakeholders to change the current face-to-face encounter policy to allow any practitioner to perform the face-to-face encounter and not limit this regulation to the certifying practitioner, a permitted NPP, or a physician or allowed practitioner with privileges who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health, as set out at § 424.22(a)(1)(v)(C). Commenters have stated that the CARES Act language allows this additional flexibility. Additionally, commenters have stated, and CMS agrees, that the current regulation text at § 424.22(a)(1)(v)(A)(1) through(4) can be read to allow NPs, CNSs, and PAs to perform the face-to-face encounter regardless of whether they certify the patient for home health services, but limits the provision of the face-to-face encounter to the certifying physician or a physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health. Therefore, stakeholders have requested that any physician, in addition to NPs, CNSs, and PAs, be allowed to perform the face-to-face encounter regardless of whether they are the certifying practitioner or whether they cared for the patient in the acute or post-acute facility from which the patient was directly admitted to home health and who is different from the certifying practitioner. Some commenters have

referenced situations in which a patient sees a physician in the same practice as the patient's primary care physician (PCP), but where the patient's PCP was unavailable to see the patient on a particular date.

We agree that it would be reasonable for the patient's PCP to certify eligibility under the Medicare home health benefit and establish the plan of care even though a different physician or allowed practitioner in the same practice conducted the face-to-face encounter. However, we note that it would not be appropriate for a practitioner who specializes in optometry to certify a patient for home health services that are needed due to orthopedic reasons. These are only a couple of examples of circumstances that could occur, and we do not plan to enumerate in this rulemaking all situations in which the certifying provider may be different than the provider who conducted the face-to-face encounter.

Regarding our original concern in limiting the face-to-face encounter to the certifying provider (or the provider who cared for the patient in the inpatient facility), we still believe physician or allowed practitioner involvement is critical from both a quality of care and program integrity perspective. However, we note that additional program integrity protections exist currently in the certification policies. To be eligible for Medicare home health services, in accordance with § 424.22(a)(1)(iv) a patient must be under the care of a physician or an allowed practitioner. Additionally, in accordance with § 424.22(a)(1)(v), the face-to-face encounter documentation must be related to the primary reason the patient requires home health services, occur in the required time frame by an allowed provider type, and the certifying practitioner must include a signature and the date of the encounter as part of the certification. Furthermore, our subregulatory guidance in the Medicare General Information, Eligibility and Entitlement Manual (Pub. 100–01, chapter 4, section 30.1) provides that physicians and allowed practitioners should complete the certification when the plan of care is established, or as soon as possible thereafter, and that it is not acceptable to wait until the end of the required time frame to complete the requirements. As such, the certification also cannot be completed after a patient is discharged from home health services.

Additionally, our subregulatory guidance in the Medicare General Information, Eligibility and Entitlement Manual (Pub. 100–01, chapter 4, section 30.1), the Medicare Benefit Policy

Manual (Pub. 100–02, chapter 7, section 30.5), and the Medicare Program Integrity Manual (Pub. 100–08, chapter 6 section 6.2.1 and 6.2.3) also supports our program integrity and quality goals. Specifically, the subregulatory guidance provides additional details on requirements that include the following: specific signature and date requirements; a requirement for an actual clinical note from the certifying practitioners for the face-to-face encounter visit; specific information that must be present in face-to-face encounter documentation; a requirement that a new face-to-face encounter is required if the patient's condition has changed; a requirement that home health eligibility must be supported by other medical entries in the certifying provider's medical record for the patient and this documentation must be available for medical reviews as needed; and a requirement that documentation of the face-to-face encounter can only be from physicians or allowed NPPs who do not have a financial relationship with the HHA.

We believe the regulations at 42 CFR 424.22(a)(1), in conjunction with the Medicare home health eligibility requirements at 42 CFR 424.22(c), finalized in the CY 2019 final rule (83 FR 56627), provide sufficient preservation of our original intent of ensuring that the home health benefit relies on the patient's physician (or subsequently, the allowed practitioner) to determine eligibility for home health services, and that the physician or NPP performing the face-to-face encounter should be a practitioner who is most knowledgeable and has firsthand information of the patient's current clinical condition when certifying the patient's eligibility for home health services and establishing a patient's plan of care.

As such, we propose to revise § 424.22(a)(1)(v)(A) to state that the face-to-face encounter must be performed by one of the following: a physician, a nurse practitioner, a clinical nurse specialist, or a physician assistant as defined at 42 CFR 484.2; or a certified nurse-midwife as defined in section 1861(gg) of the Act as authorized by State law. We also propose to remove § 424.22(a)(1)(v)(C), which limits the face-to-face encounter to the certifying physician or allowed practitioner unless the encounter is performed by either of the following:

- A certified nurse midwife as described in paragraph (a)(1)(v)(A)(4) of this section.
- A physician, physician assistant, nurse practitioner, or clinical nurse specialist with privileges who cared for

the patient in the acute or post-acute facility from which the patient was directly admitted to home health and who is different from the certifying practitioner.

The proposed additional flexibility should decrease ambiguity regarding which providers are able to complete the face-to-face encounter and potentially improve access to home health services by increasing the number of providers allowed to perform the face-to-face encounter. These proposed revisions would also address concerns that the current regulations do not align with the CARES Act language. We solicit comments on these proposed revisions to 42 CFR 424.22(a)(1)(v).

III. Home Health Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

The HH QRP is authorized by section 1895(b)(3)(B)(v) of the Act. Section 1895(b)(3)(B)(v)(II) of the Act requires that, for 2007 and subsequent years, each home health agency (HHA) submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary shall reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points pursuant to section 1895(b)(3)(B)(v)(I) of the Act. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, as further reduced by the productivity adjustment (except in 2018 and 2020) described in section 1886(b)(3)(B)(xi)(II) of the Act, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the HH PPS for a year being less than payment rates for the preceding year. Section 1890A of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890 of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the HH QRP. The HH QRP regulations can be found at 42 CFR 484.245 and 484.250.

B. Summary of the Provisions of This Proposed Rule

In accordance with the statutory authority at section 1895(b)(3)(B)(v) of the Act, we are proposing the following policies and requests for information:

We are proposing to remove the “COVID–19 Vaccine: Percent of Patients Who Are Up to Date” measure and the item related to the measure and corresponding data element. CMS is proposing the removal of four assessment items: one Living Situation item, two Food items, and one Utilities item. We are also proposing to revise the policy to allow for providers that fail to provide complete, timely data to CMS to submit a request for reconsideration if they can demonstrate full compliance. In very limited circumstances, we would permit the HHA to request an extension to file a reconsideration request if the HHA was affected by an

extraordinary circumstance beyond the control of the HHA (that is, a natural disaster such as a hurricane tornado or earthquake) during the 30-day reconsideration period. CMS is also proposing to implement a revised HHCAHPS Survey beginning with the April 2026 sample month. This rule also includes a proposal to update regulatory text to account for all-payer data submission of OASIS data. We are seeking feedback on a potential change to the final data submission deadline from 4.5 months to 45 days after the close of the period. We are also seeking feedback on the digital quality measurement (DQM) transition for HHAs. We aim to solicit feedback from the public on the current adoption of health information technology (IT) and standards including Fast Healthcare Interoperability Resources (FHIR), what related challenges or barriers HHAs are

facing. Finally, we are seeking input on future HH QRP quality measure (QM) concepts of interoperability, cognitive function, nutrition, and patient well-being.

For a detailed discussion of the considerations, we historically use for measure selection for the HH QRP quality, resource use, and other measures, we refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68696). In the CY 2019 HH PPS final rule with comment period (83 FR 56548 through 56550), we finalized the factors we consider for removing previously adopted HH QRP measures.

C. Quality Measures Currently Adopted for the CY 2026 HH QRP

The HH QRP currently includes 19 measures for the CY 2026 program year, as described in table 30.

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TABLE 30: MEASURES CURRENTLY ADOPTED FOR THE CY 2026 HH QRP

Short Name	Measure Name & Data Source
QM Name	OASIS-based
Ambulation	Improvement in Ambulation/Loocomotion (CBE #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (CBE #0674).
Bathing	Improvement in Bathing (CBE #0174).
Bed Transferring	Improvement in Bed Transferring (CBE # 0175).
Patient COVID-19 Vaccination	COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP.
DC Function	Discharge Function Score
Dyspnea	Improvement in Dyspnea.
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medications (CBE #0176).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation of Care (CBE #0526).
TOH-Provider	Transfer of Health Information to Provider-Post-Acute Care ¹
TOH-Patient	Transfer of Health Information to Patient-Post-Acute Care ¹
QM Name	Claims-based
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) (CBE #3477)
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.
PPH	Home Health Within Stay Potentially Preventable Hospitalization
QM Name	HHCAPHS-based
CAHPS Home Health Survey	CAHPS® Home Health Care Survey (experience with care) (CBE #0517) ² - How often the HH team gave care in a professional way. - How well did the HH team communicate with patients. - Did the HH team discuss medicines, pain, and home safety with patients. - How do patients rate the overall care from the HHA. - Will patients recommend the HHA to friends and family.

¹ Data collection delayed due to the COVID-19 public health emergency for the TOH-Patient and TOH-Provider.

² The HHCAPHS has five components that together are used to represent one CBE-endorsed measure.

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D. Proposed Removal of the “COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date” (Patient/Resident COVID-19 Vaccine Measure) Beginning With the CY 2026 HH QRP

We refer readers to the CY 2024 HH PPS final rule, where we adopted the “COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date” (“Patient/Resident COVID-19 Vaccine measure”) into the HH QRP (88 FR 77762 through 77764). For the HH QRP, we propose to remove the Patient/Resident COVID-19 Vaccine measure beginning with the CY 2026 HH QRP under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program (§ 484.245(b)(3)(viii)). The estimated burden of collecting this information annually across all 11,904 active HHAs is 47,168 hours at a cost of \$4,326,249. We refer readers to section VII of this proposed rule for more details on the estimated burden reduction related to this proposal.

When we adopted the Patient/Resident COVID-19 Vaccine measure, COVID-19 continued to be a major challenge for HHAs, with older adults at a significantly higher risk of mortality, severe disease, and death following infection (88 FR 77762). HHAs have expressed concerns about data collection challenges and increased provider burden in collecting patient immunization data.⁸ Providers were required to integrate the required Patient/Resident COVID-19 Vaccine OASIS item into their assessment instrument and ensure accurate assessment for all their patients. While preventing the spread of COVID-19 remains a public health goal, the number of COVID-19 cases and deaths⁹ is declining, and we believe the continued costs and burden to providers of reporting this measure outweigh the benefit of continued information collection on COVID-19 vaccination coverage among patients in HHAs. For the COVID-19 items collected at transfer of care, death at home, and discharge, we estimate a decrease in clinician cost of \$4,326,249 or \$363 (\$4,326,249/11,904) for each of the 11,904 active HHAs. We refer readers to

section VII.A.3. of this proposed rule for more details on this estimated burden reduction.

We propose that, effective with assessments completed on or after the date of publication of the CY 2026 HH PPS final rule, the data from the “Patient/Resident COVID-19 Vaccination is Up to Date” OASIS item (O0350) would no longer be used in the calculation of the Patient/Resident COVID-19 Vaccine measure, and the measure itself would be withdrawn pursuant to measure removal factor eight (set out at 42 CFR

484.245(b)(3)(viii)). We propose to remove the Patient/Resident COVID-19 Vaccination is Up to Date item (O0350) from the OASIS effective April 1, 2026, since it is not technically feasible to remove this item earlier. However, under our proposal, until this item could be removed from the OASIS, HHAs may submit any valid response (0—No, 1—Yes or dash) on a Transfer, Death at home, or Discharge OASIS assessment, without any future quality measure implications. Note that the item must be completed with one of these three valid responses (must not be left blank) in order for the submitted assessment to not be rejected by the iQIES under existing submission specification edits.

We invite public comment on our proposal to remove the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure from the HH QRP beginning with the CY 2026 HH QRP.

E. Proposed Removal of Four Standardized Patient Assessment Data Elements Beginning With the CY 2026 HH QRP

We refer readers to the CY 2025 HH PPS final rule (88 FR 88433 through 88439) where we finalized the adoption of four items as standardized patient assessment data elements under the social determinants of health (SDOH) category: one item for Living Situation (R0310); two items for Food (R0320A and R0320B); and one item for Utilities (R0330). As finalized in the CY 2025 HH PPS final rule, HHAs would be required to report these data elements using the OASIS beginning with patients discharged in the CY 2027 HH QRP and each program year after (89 FR 88433 through 88439).

In this proposed rule, we are proposing to remove these four standardized patient assessment data elements under the SDOH category as we acknowledge the burden associated with these items at this time. We continuously look for ways to balance the need for data collections regarding

quality care and the burden of data collection on health care providers. CMS has a goal to facilitate improved health care delivery by requiring different systems and software applications to communicate and exchange data. Therefore, we would like to work towards the workflow for these specific data elements being part of a low burden interoperable electronic system. The focus would turn towards how these data and associated recommendations exchanged can improve care coordination, efficiency, reduction in errors and patient experience.

As health information technology (HIT) advances and interoperability of data becomes more standardized, the burden to collect and share clinical data on these and other relevant patient information would become less burdensome allowing for better outcomes for HH patients and their families. The objectives of the HH QRP continue to be the improvement of care, quality and health outcomes for all patients through transparency and quality measurement, while not imposing undue burden on essential health providers. HHAs and providers across the industry play a vital role in improving the health of all patients, including those who may be experiencing unstable housing, food insecurity or challenges paying utilities. At the same time, we recognize the burden that the collection of these additional data would impose on already overextended staff. We also acknowledge the additional cost and resources HHAs would bear for training HH staff and altering their workflows if they were required to collect and submit these items. The objectives of the HH QRP continue to be the improvement of care, quality and health outcomes for all patients through transparency and quality measurement. The estimated savings from not collecting this information annually across all 11,904 HHAs is 158,835 hours, with total savings of \$13,484,033 (or \$1,132 per HH). We refer readers to section VII.A.3. of this proposed rule for more details on this estimated burden reduction.

Under our proposal, HHAs would no longer be required to collect and submit Living Situation (R0310), Food (R0320A and R0320B), and Utilities (R0330) beginning with patients discharged on or after April 1, 2026. Under our proposal, these items would not be required to meet HH QRP requirements beginning with the CY 2026 HH QRP.

We invite public comment on our proposal to remove four standardized patient assessment data elements collected under the SDOH category from

⁸ Standing Technical Expert Panel for the Development, Evaluation, and Maintenance of Post-Acute Care (PAC) and Hospice Quality Reporting Program (QRP) Measurement Sets Summary Report December 15, 2023. <https://www.cms.gov/files/document/december-2023-pac-and-hospice-cross-setting-tep-summary-report.pdf>.

⁹ Provisional COVID-19 Deaths, by Week, in The United States, Reported to CDC. Accessed on March 18, 2025, via https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00.

the HH QRP beginning with the CY 2026 HH QRP.

F. Amending the Data Non-Compliance Reconsideration Request Policy and Process Beginning With the CY 2026 HH QRP

1. Background

The HH QRP reconsiderations and appeals process was finalized in the CY 2013 HH PPS final rule (77 FR 67096). At the conclusion of the required quality data reporting and submission period, we review the data received from each HHA during that reporting period to determine if the HHA met the HH QRP reporting requirements. HHAs that are found to be non-compliant with the HH QRP reporting requirements for the applicable calendar year will receive a 2-percentage point reduction to its market basket percentage update for that calendar year. In the CY 2018 HH PPS final rule (82 FR 52738 through 51740), CMS finalized a process for HHAs to request and for us to grant exceptions and extensions for the reporting requirements of the HH QRP for one or more quarters beginning with the CY 2019 HH QRP when there are certain extraordinary circumstances outside the control of the HHA. When an exception or extension is granted, we finalized that we would not reduce the HHA's PPS payment for failure to comply with the requirements of the HH QRP.

In that rule, we finalized a policy that, in very limited circumstances, CMS could grant a request by an HHA to extend the proposed deadline for their reconsideration requests (82 FR 52738 through 51740). We stated that, to extend the deadline, HHAs would have to request an extension and demonstrate that "extenuating circumstances" existed which prevented the filing of the reconsideration request by the proposed 30-day deadline (82 FR 52738 through 51740).

In the CY 2018 HH PPS final rule (82 FR 51752), we codified the reconsideration policy and process for HHAs at § 484.250. As codified, our regulation at § 484.250 addressed how we send our written notification of non-compliance to an HHA, the process for an HHA to request reconsideration, what information an HHA must include with its reconsideration request (for example, documentation that demonstrates the HHA's compliance HH QRP requirements), and how we would notify the HHA of our final decision regarding its reconsideration request. In 2019, we moved the regulatory text to § 484.245 and updated and clarified the regulatory text in the CY 2020 HH PPS final rule (84 FR 60645).

We have become aware that there are inconsistencies in our preamble and regulation text regarding HHA requests for reconsideration. On this basis, in this proposed rule, we seek to address these inconsistencies.

2. HH QRP Reconsideration Policy: Proposal To Amend and Codify Requirements Related to Requests for Extension To File Reconsideration Request Beginning With the CY 2027 HH QRP

As noted previously, in the CY 2018 HH PPS final rule (82 FR 51738 through 51740), we provided that, in very limited circumstances, we may grant a request by an HHA to extend the deadline to submit its reconsideration request, so long as the HHA requested the extension and demonstrated that extenuating circumstances existed that prevented it from filing a reconsideration request by the 30-day deadline (82 FR 51738 through 51740). However, we did not codify this policy—permitting HHAs to request an extension to file their reconsideration request—in our regulation text at § 484.245(d).

In implementing this finalized policy, we have noted an area where further clarity would be beneficial to HHAs. Specifically, we have noted that HHAs may benefit from clearly demarcated deadlines. Although we believe an HHA would have an interest in asking for an extension to file a reconsideration request prior to the deadline, our policy currently does not specify a deadline for an HHA to submit its request for such an extension (82 FR 51738 through 51740). Our policy also provides that, to support such request, the HHA must demonstrate that extenuating circumstances existed that prevented filing the reconsideration request by the 30-day deadline (82 FR 51738 through 51740). However, we have not specified a deadline from when the extenuating circumstances occurred. We believe HHAs may benefit from further specificity by setting a deadline for submitting a request to extend the deadline to file a reconsideration request.

On this basis, we propose to amend our reconsideration policy as codified at § 484.245(d) to permit a HHA to request, and CMS to grant, an extension to file a request for reconsideration of a non-compliance determination if, during the period to request a reconsideration as set forth in § 484.245(d), the HHA was affected by an extraordinary circumstance beyond the control of the HHA (for example, a natural or man-made disaster such as a cyber-attack, hurricane, tornado, or earthquake). We

propose that the HHA submit its request for an extension to file a reconsideration request to CMS via email no later than 30 calendar days from the date of the written notification of non-compliance. We propose that the HHA's extension request, submitted to CMS, must contain all of the following information: (1) the CCN for the HHA; (2) the business name of the HHA; (3) the business address of the HHA; (4) certain contact information for the HHA's chief executive officer or designated personnel; (5) a statement of the reason for the request for the extension; and (6) evidence of the impact of the extraordinary circumstances, including, for example, photographs, newspaper articles, and other media. We propose to codify this process at § 484.245(d)(5).

We further propose that CMS would notify the HHA in writing of its final decision regarding its request for an extension to file a reconsideration of non-compliance request via an email from CMS. We propose to notify the HHA in writing via email because this would allow for more expedient correspondence with the HHA, given the 30-day reconsideration timeframe. We propose to codify this process at § 484.245(d)(6).

We note that we are considering proposing similar modifications across all post-acute care setting quality reporting programs to more closely align the reconsideration processes.

We invite comment on these proposals to amend the HH QRP Reconsideration policy to permit HHAs to request an extension to file a reconsideration request beginning with the CY 2027 HH QRP and to codify this proposed policy and process at § 412.634(d)(5) and (d)(6).

3. Proposal To Codify the Bases on Which CMS Can Grant a Reconsideration Request

As discussed previously, in CY 2013 HH PPS final rule, we stated that, after we review an HHA request for reconsideration, we may reverse our initial finding of non-compliance if: (1) the HHA provides proof of compliance with all requirements during the reporting period; or (2) the HHA provides adequate proof of a valid or justifiable excuse for non-compliance if the HHA was not able to comply with requirements during the reporting period (77 FR 67096). We also stated that we will uphold an initial finding of non-compliance if the HHA cannot show any justification for non-compliance (77 FR 67096).

As previously discussed, we codified our reconsideration policy at § 484.245(d) in the CY 2013 HH PPS

final rule (77 FR 67096). Our regulation at § 484.245(d)(3) requires that an HHA's request for reconsideration include accompanying documentation that demonstrates the HHA's compliance with the HH QRP requirements. Then, we will notify the HHA in writing regarding our final decision on its reconsideration request (§ 412.634(d)(4)).

We believe it would be beneficial for HHAs if we codify our specific bases for granting a reconsideration request in our regulation at § 484.245(d). These have not been previously outlined in regulatory text and CMS has outlined these details for clarity for any HHA seeking an extension in the reconsideration process.

On these bases, we propose to modify our reconsideration policy to provide that we will grant a timely request for reconsideration and reverse an initial finding of non-compliance, only if CMS determines that the HHA was in full compliance with the HH QRP requirements for the applicable program year. We would consider full compliance with the HH QRP requirements to include CMS granting an exception or extension to HH QRP reporting requirements under our extraordinary circumstance exception and extension (ECE) policy at § 484.245(c). However, to demonstrate full compliance with our ECE policy, the HHA would need to comply with our ECE policy's requirements, including the specific scope of the exception or extension as granted by CMS.

We propose to modify § 484.245(d)(4) to codify this modified policy in our regulation. We note that we are considering proposing similar modifications across all post-acute care setting quality reporting programs to more closely align the reconsideration processes.

We invite comment on these proposals to amend the bases by which we grant a reconsideration request under the HH QRP reconsideration policy and to codify this proposed policy at § 484.245(d)(5).

G. Updates to Requirements for OASIS All-Payer Data Submission

1. Statutory Authority and Background

Section 1891(d) of the Act, cross-referencing section 1891(c)(2)(C)(i)(I) of the Act (section 4021(b) of Pub. L. 100–203 (December 22, 1987)) requires the Secretary to develop a comprehensive assessment for Medicare-participating HHAs. In 1993, CMS (then known as HCFA) developed an assessment instrument that identified each patient's

need for home care and the patient's medical, nursing, rehabilitative, social and discharge planning needs. As part of this assessment, Medicare-certified HHAs were required to use a standard core assessment data set, the Outcome and Assessment Information Set (OASIS). As part of the home health assessment, the statute requires a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care provided by the HHA. OASIS is the designated assessment instrument for use by an HHA in complying with the requirement and HHAs must submit the data collected by the OASIS assessment to CMS as an HHA condition of participation (42 CFR part 484.45).

Section 704 of the Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, December 12, 2003) “suspended” the legal authority of the Secretary to require HHAs to report non-Medicare and non-Medicaid patient data to CMS until at least two months after the Secretary published final regulations on CMS's collection and use of OASIS data following the submission of a report to Congress on the study required under section 704(c) of the MMA. Subsequently, CMS conducted the study from 2004 to 2005 and submitted a report¹⁰ to Congress in 2006 titled “The OASIS Study: The Costs and Benefits Associated with the Collection of Outcome and Assessment Information Set (OASIS) Data on Private Pay Home Health Patients—Report to Congress.” While the 2006 report recommended that the suspension continue, the passage of the Improving Medicare Post-Act Care Transformation (IMPACT) Act (Pub. L. 113–115) in 2014 required CMS to create a uniform quality measurement system that allows CMS to compare outcomes across post-acute care (PAC) providers.

The final rule¹¹ titled, “Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements” finalized the requirement for HHAs to report OASIS data on all patients, regardless of payer, for the applicable 12-month performance period (example

July 1, 2025–June 30, 2026) (87 FR 66862). With the CY 2025 HH PPS final rule, CMS established that start of care (SOC) is the first assessment that can be submitted for a non-Medicare/non-Medicaid patient, either on or after January 1, 2025, for the phase-in (voluntary) period or on or after July 1, 2025, for the mandatory period. CMS would use the M0090 “Date Assessment Completed” date of the SOC assessment to identify non-Medicare/non-Medicaid patient assessments in the phase-in and mandatory periods (89 FR 88439 through 88441). This ended the suspension of the OASIS data collection on non-Medicare and non-Medicaid HHA patients. As discussed in the final rule, the most accurate representation of the quality of care furnished by HHAs is best captured by calculating the assessment-based measures rates using OASIS data submitted on all HHA patients receiving skilled care, regardless of payer.

2. Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements (§§ 484.45(a) and 484.55(d)(1)(i))

Section 484.45(a) of the HHA CoPs currently requires an HHA to encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each beneficiary with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary. To align with the transition to OASIS all-payer submission requirements as outlined in the CY 2023 Home Health PPS final rule, we are proposing at § 484.45(a) to remove the term “beneficiary” and replace it with the term “patient.” Thus, § 484.45(a) would read, if finalized as proposed, “An HHA must encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each patient with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the patient.”

Patients must receive, and an HHA must provide, a comprehensive assessment no later than five calendar days after the start of care. The comprehensive assessment not only examines patients' current health, psychosocial, functional, and cognitive status, but also must incorporate the most current version of the OASIS data items. This includes clinical record items, patient history, supportive assistance, etc. Currently, the comprehensive assessment, including administration of OASIS, must be

¹⁰ <https://www.cms.gov/files/document/cms-oasis-study-all-payer-data-submission-2006.pdf>.

¹¹ <https://www.federalregister.gov/documents/2022/11/04/2022-23722/medicare-program-calendar-year-cy-2023-home-health-prospective-payment-system-rate-update-home>.

updated and revised as frequently as the patient's condition warrants, but not less frequently than the last five days of every 60 days beginning with the start-date of care. Language at § 484.55(d)(1)(i) references a "beneficiary elected transfer" in reference to one scenario in which an OASIS assessment would be updated. To support the transition to OASIS all-payer submission requirements, we are also proposing to remove the term "beneficiary" at § 484.55(d)(1)(i).

These technical changes to update terminology would further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services and align the language in the CoPs with the requirements finalized in the CY 2023 and CY 2025 Home Health PPS final rules. We note that this policy does not change current patient exemptions for OASIS, which are as follows: patients under the age of 18; patients receiving maternity services; and patients receiving only personal care, housekeeping, or chore services.

H. Proposed HHCAHPS Survey Updates

a. Survey and Measure Changes

Based on feedback from patients and interested parties, CMS launched an effort to update and shorten the Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) survey. CMS conducted a mode experiment with 100 HHAs in 2022. The experiment tested a web-mail mode and a revised survey instrument. The revised survey is shorter than the current survey and includes new

questions on topics suggested by interested parties. Specifically, changes to the survey and the quality measures derived from testing include the following:

- Addition of three new questions to assess new topics of importance to patients:
 - ++ Whether the care provided helped the patient take care of their health.
 - ++ Whether the patient's family/friends were given sufficient information and instructions.
 - ++ Whether the patient felt the staff cared about them "as a person."
- Removal of questions or topics of less importance to patients (that is, six questions about medications were reduced to two questions).
- The following 4 questions were removed:
 - ++ Whether someone asked to see all the prescription and over-the-counter medicines the patient was taking.
 - ++ Whether the patient is taking any new prescription medicines or whether the patient's medicines have changed.
 - ++ Whether home health providers talked to the patient about the purpose for taking new or changed prescription medicines.
 - ++ Whether home health providers talked to the patient about when to take the medicines.
- Removal of questions not currently used in public reporting composites (that is, three questions on which type of staff served the patient—nurse, physical or occupational therapist, and home care aide).
- Removal of one question which did not perform well in testing to stand alone or fit into one of the revised composite measures:

- Whether the patient got information about what care and services they would get when they first started getting home health care.

- Minor text changes to selected existing questions to help clarify the question or response options, based on feedback from patients.

The revised HHCAHPS Survey, including the revised Care of Patients and Communications between Providers and Patients measures, and the three stand-alone measures that remain from the current Specific Care Issues measure were reviewed as part of the 2025 Measures Under Consideration list (MUC2024–054, –055, –061, –062, & –063) through the Pre-Rulemaking Measure Review (PRMR) Post-Acute Care/Long-Term Care (PAC/LTC) Committee. The PRMR PAC/LTC Committee recommended four out of the five measures without any conditions and one of the measures with conditions, such as stratifying the survey data for analysis and including greater detail about the types of medications. For more information, please see <https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf>. Due to the very favorable recommendations from the PRMR, we are proposing to move forward with the five measures. CMS is proposing to implement the revised HHCAHPS Survey beginning with the April 2026 sample month. Table 31 provides a comparison of the current and proposed HHCAHPS Survey measures.

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TABLE 31: CURRENT AND PROPOSED CHANGES TO HHCAHPS SURVEY MEASURES

Measure	Item(s) in Current Measure	Item(s) in Proposed Revised or New Measure
Care of Patients	In the last 2 months of care, how often did home health providers from this agency seem informed and up to date about all the care or treatment you got at home? (Q9)	In the last 2 months of care, how often did home health staff from this agency seem to be aware of all the care or treatment you were getting at home? (Q6)
	In the last 2 months of care, how often did home health providers from this agency treat you as gently as possible? (Q16)	In the last 2 months of care, how often did home health staff from this agency treat you with care – for example, when moving you around or changing a bandage? (Q7)
	In the last 2 months of care, how often did home health providers from this agency treat you with courtesy and respect? (Q19)	In the last 2 months of care, how often did home health staff from this agency treat you with courtesy and respect? (Q10)
	N/A (not on current survey)	In the last 2 months of care, how often did you feel that home health staff from the agency cared about you as a person? (Q11)
	N/A (not on current survey)	In the last 2 months of care, how often have the services you received from this agency helped you take care of your health? (Q13)
	In the last 2 months of care, did you have any problems with the care you got through this agency? (Q24)	N/A (removed from revised survey)
Communications between Providers and Patients	When you first started getting home health care from this agency, did someone from the agency tell you what care and services you would get? (Q2)	N/A (removed from revised survey)
	In the last 2 months of care, how often did home health providers from this agency keep you informed about when they would arrive at your home? (Q15)	In the last 2 months of care, how often did home health staff from this agency keep you informed about when they would arrive at your home? (Q5)
	In the last 2 months of care, how often did home health providers from this agency explain things in a way that was easy to understand? (Q17)	In the last 2 months of care, how often did home health staff from this agency explain things in a way that was easy to understand? (Q8)
	In the last 2 months of care, how often did home health providers from this agency listen carefully to you? (Q18)	In the last 2 months of care, how often did home health staff from this agency listen carefully to you? (Q9)
	N/A (not on current survey)	In the last 2 months of care, did home health staff from this agency provide your family or friends with information or instructions about your care as much as you wanted? (Q12)
	In the last 2 months of care, when you contacted this agency's office did you get the help or advice you needed? (Q22)	When you contacted this agency's office, did you get the help or advice you needed? (Q16)

Measure	Item(s) in Current Measure	Item(s) in Proposed Revised or New Measure
	When you contacted this agency's office, how long did it take for you to get the help or advice you needed? (Q23)	N/A (removed from revised survey)
Specific care issues	When you first started getting home health care from this agency, did someone from the agency talk with you about how to set up your home so you can move around safely? (Q3)	- When you first started getting home health care from this agency, did someone from the agency talk about ways to help make your home safer? For example, they may have suggested adding grab bars in the shower or removing tripping hazards. (Q2) - Removed composite; reporting as standalone item
	When you started getting home health care from this agency, did someone from the agency talk with you about all the prescription and over-the-counter medicines you were taking? (Q4)	- Has someone from the agency ever reviewed the prescribed and over-the-counter medicines you were taking? For example, they might have asked you to show them your medicines and talked with you about how and when to take each one. (Q3) - Removing composite; reporting as standalone item
	When you started getting home health care from this agency, did someone from the agency ask to see all the prescription and over-the-counter medicines you were taking? (Q5)	N/A (removed from revised survey)
	In the last 2 months of care, did home health providers from this agency talk with you about the side effects of these medicines? (Q14)	- In the last 2 months of care, did home health staff from this agency talk with you about any side effects of your medicines? (Q4) - Removing composite; reporting as standalone item
	In the last 2 months of care, did you and a home health provider from this agency talk about pain? (Q10)	N/A (removed from revised survey)
	In the last 2 months of care, did home health providers from this agency talk with you about the purpose for taking your new or changed prescription medicines? (Q12)	N/A (removed from revised survey)
	In the last 2 months of care, did home health providers from this agency talk with you about when to take these medicines? (Q13)	N/A (removed from revised survey)
Overall rating	We want to know your rating of your care from this agency's home health providers. Using any number from 0 to 10, where 0 is the worst home health care possible and 10 is the best home health care possible, what number would you use to rate your care from this agency's home health providers? (Q20)	We want to know your rating of your care from this agency's home health staff. Using any number from 0 to 10, where 0 is the worst home health care possible and 10 is the best home health care possible, what number would you use to rate your care from this agency's home health staff? (Q14)
Willingness to recommend	Would you recommend this agency to your family or friends if they needed home health care? (Q25)	Would you recommend this agency to your family or friends if they needed home health care? (Q17)

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b. Impact on Public Reporting and Star Ratings

HHCAHPS Survey measure scores are calculated across four rolling quarters and are published quarterly for all HHAs over the reporting period. The Summary Star Rating is currently based on the Overall Rating of Care and the three composite measures that are equally weighted. We are proposing to calculate the Summary Rating based on the Overall Rating of Care, the two modified composite measures (Care of Patients and Communications between Providers and Patients), and the three new stand-alone measures related to talking about home safety, reviewing prescribed and over-the-counter medicines, and talking about medicine side effects. In the calculation of the Summary Star Rating, we are proposing that the Overall Rating of Care and two modified composite measures would each have a weight of 1 and each of the three new stand-alone measures would have a weight of one-third. The Summary Star Ratings would continue to be calculated using four rolling quarters and would be publicly reported for all HHAs with 40 or more completed surveys over the reporting period. Star Ratings are updated every quarter. To determine what impact the changes to the survey measures would have on public reporting, CMS considered the nature of the measure change. As Talk About Home Safety, Review Medicines, and Talk About Medicine Side Effects are new measures for the HHCAHPS Survey, since they would be reported individually, we would have to wait to introduce public reporting until we have four quarters of data. Although the revised Care of Patients measure is conceptually similar to the current Care of Patients measure, we believe the change (adding two new questions and dropping one question) is substantive and the revised measure should be treated as new for purposes of public reporting and Star Ratings. Similarly, the revised Communications Between Providers and Patients measure is also conceptually similar to the current Communications Between Providers and Patients measure; however, the change (dropping two questions and adding one new question) is substantive and the revised measure should be treated as new for purposes of public reporting and Star Ratings. As such, we propose waiting to publicly report the new versions of Care of Patients and Communications Between Providers and Patients until we have four quarters of data. We anticipate that the first Care Compare refresh in which publicly

reported measures scores would be updated to include the new measures would be October 2027, with scores calculated using data from Q2 2026 through Q1 2027. In the interim period, measure scores would be made available to HHAs confidentially via their Provider Preview reports on the HHCAHPS Survey website after two full quarters of data are submitted.

We believe the change to the Overall Rating measure (minor wording change from “provider” to “staff”) is non-substantive (*i.e.*, does not meaningfully change the measure) and along with the unchanged Willingness to Recommend the Agency measure, both measures can continue to be publicly reported in the transition period between the current and new surveys. During the transition period, scores and Star Ratings for the Overall Rating and Willingness to Recommend measures would be calculated by combining scores from quarters using the current and new survey and continue to be reported.

c. Survey Administration Changes

No survey administration changes are proposed with the new survey.

d. Case-Mix and Mode Adjustments

Prior to public reporting, HHAs’ HHCAHPS Survey scores are adjusted for the effects of case mix. Case mix refers to characteristics of the patient that are not under control of the HHA that may affect reports of home health experiences. Case-mix adjustment is performed within each quarter of data after data cleaning. The current case-mix adjustment model includes the following variables: patient age, patient education, self-reported overall health, self-reported mental health, diagnosis of schizophrenia or dementia, whether the patient lives alone, whether the patient or a proxy answered the survey, and language in which the survey was completed. The model used and adjustments are updated quarterly and are available on the HHCAHPS website at this link: <https://homehealthcahps.org/General-Information/Archived-Publicly-Reported-Data> Based on testing the revised survey in a 2022 Mode Experiment, CMS reviewed the variables included in the case-mix adjustment models currently in use for the HHCAHPS Survey to determine if any changes needed to be introduced along with the revised survey. We found that while no case-mix variables need to be added, the diagnosis adjustments were no longer significant. As such, CMS proposes to drop the adjustment for diagnoses of schizophrenia or dementia with the revised survey.

Using data from the 2022 Mode Experiment, CMS also tested for whether there were impacts in how someone responds to the survey based on the mode of survey administration. Mode effects were observed with the 2022 Mode Experiment, so CMS is proposing to add a mode adjustment in addition to the case-mix adjustment, with the revised survey. Case-mix adjustment would be performed within each quarter of data after data cleaning and before mode adjustment. When we make mode adjustments, it is necessary to choose one mode as a reference mode. One can then interpret all adjusted responses from all modes as if they had been surveyed in the reference mode. CMS would use mail-only as the reference mode for the HHCAHPS Survey, because it is the most used mode for HHCAHPS. The choice of mail mode as the reference mode does not indicate that mail mode is preferable to other approved modes in any way. In the 2022 HHCAHPS Survey mode experiment, telephone-only respondents were more negative in their evaluations of care relative to mail-only respondents across the HHCAHPS measures. The mode adjustments are generally small—most are around 2 percentage points.

Please see the HHCAHPS Revised Survey Mode Adjustments on <https://homehealthcahps.org> for the mode adjustments if these measures are finalized through rulemaking.

We invite public comment on the HHCAHPS Survey proposals.

1. HH QRP Quality Measure Concepts Under Consideration for Future Years—Request for Information

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the quality measure concepts under consideration listed in Table 32 for future years of the HH QRP. In the CY 2024 HH PPS proposed rule (88 FR 43738 through 43740), we included a request for information (RFI) on a set of principles for selecting and prioritizing HH QRP measures, identifying measurement gaps, and suitable measures for filling these gaps. We refer readers to the CY 2024 HH PPS final rule (88 FR 77773 through 77774) for a summary of the public comments received in response to the RFI.

We are seeking input on four concepts for future measures for the HH QRP.

1. Interoperability

We are seeking input on the quality measure concept of interoperability, focusing on information technology (IT) systems’ readiness and capabilities in the HH setting. Title XXX of the Public

Health Service Act defines “interoperability” in part, and with respect to health IT, as health IT that enables the secure exchange of electronic health information with, and use of electronic health information from, other health IT without requiring special efforts by the user.¹² The definition further states that interoperability of health IT allows for complete, including by providers and patients, access, exchange, and use of electronically accessible health information for authorized uses under applicable State or Federal law.¹³ We request input and comment on approaches to assessing interoperability in the HH setting, for instance, measures that address or evaluate the level of readiness for interoperable data exchange, or measures that evaluate the ability of data systems to securely share information across the spectrum of care.

2. Cognitive Function

Illnesses associated with limitations in cognitive function, which may include stroke, traumatic brain injuries, dementia, and Alzheimer’s disease, affect an individual’s ability to think, reason, remember, problem-solve, and make decisions. The IMPACT Act identifies cognitive function as a key quality measure domain, and an area for inclusion as a standardized assessment data element.

Two sources of information on cognitive function currently collected in HHAs are the Brief Interview for Mental Status (BIMS) and Confusion Assessment Method (CAM®).¹⁴ Both the BIMS and CAM have been incorporated into the OASIS. Scored by providers via direct observation, the BIMS is used to

determine orientation and the ability to register and recall new information. The CAM assesses the presence of inattention, disorganized thinking, and level of consciousness.

The BIMS and CAM include items representing different aspects of cognitive function, from which quality measures may be constructed. Although these instruments have been subjected to feasibility, reliability, and validity testing, additional development and testing would be required prior to transforming the concepts reflected in the BIMS and CAM (example temporal orientation, recall) into fully specified measures for implementation in the HH QRP.

This RFI is requesting input on cognitive functioning measures that may be available for immediate use, or that may be adapted or developed for use in the HH QRP, using the BIMS or the CAM. In addition to comment on specific measures and instruments, CMS seeks input on the feasibility of measuring improvement in cognitive functioning during a HH stay, which typically averages 56 days;¹⁵ the cognitive skills (example executive functions) that are more likely to improve during an HHA stay; conditions for which measures of maintenance—rather than improvement in cognitive functioning—are more practical; and the types of intervention that have been demonstrated to assist in improving or maintaining cognitive functioning.

3. Well-Being

We are seeking input on a quality measure concept of well-being. Well-being is a comprehensive approach to

disease prevention and health promotion, as it integrates mental, social, and physical health while emphasizing preventative care to proactively address potential health issues.¹⁶ This comprehensive approach emphasizes person-centered care by promoting well-being of patients and their family members. We are seeking comments on tools and measures that assess for overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, fulfillment, and self-care.

4. Nutrition

Finally, we are seeking input on a quality measure concept of nutrition. Assessment for nutritional status may include various strategies, guidelines, and practices designed to promote healthy eating habits and ensure individuals receive the necessary nutrients for maintaining health, growth, and overall well-being. This also includes aspects of health that support or mediate nutritional status, such as physical activity and sleep. In this context, preventable care plays a vital role by proactively addressing factors that may lead to poor nutritional status or related health issues. These efforts not only support optimal nutrition but also work to prevent conditions that could otherwise hinder an individual’s health and nutritional needs. We are seeking feedback on tools and frameworks that promote healthy eating habits, exercise, nutrition, or physical activity for optimal health, well-being, and best care for all.

TABLE 33: MEASURE CONCEPTS UNDER CONSIDERATION FOR FUTURE YEARS OF THE HH QRP

Quality Measure Concepts
Interoperability
Cognitive Function
Well-being
Nutrition

¹² 21st Century Cures Act, 42 U.S.C. 300jj(9) (2016).

¹³ 21st Century Cures Act, 42 U.S.C. 300jj(9) (2016).

¹⁴ Centers for Medicare & Medicaid Services. Long-Term Care Hospital Continuity Assessment

Record and Evaluation (CARE) Data Set Version 5.0. Effective October 1, 2022. <https://www.cms.gov/files/document/lth-care-data-set-version-50-planned-discharge-final.pdf>.

¹⁵ Based on home health episodes ending in CY2021 (the most recent year for which complete data are available).

¹⁶ Well-Being Concepts. CDC Archives. *WHPL_Canon_WB_Well-Being_Concepts_HRQOL_CDC_2017.pdf*.

We intend to use this input to inform our future measure development efforts.

J. Potential Revision of the Final Data Submission Deadline Period From 4.5 Months to 45 Days—Request for Information (RFI)

Section 1895(b)(3)(B)(v)(I) of the Act states that for 2007 and each subsequent year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points if a home health agency does not submit quality data to the Secretary in accordance with subclause (II) for such a year. Section 1899B(f)(1) of the Act also requires the Secretary to provide confidential feedback reports to PAC providers on the performance of such PAC providers for quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning 1 year after the applicable specified application date. Further, section 1899B(g) of the Act requires the Secretary to establish procedures for making available to the public information regarding the performance of individual PAC providers for quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning not later than 2 years after the applicable specified application date. The procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act for similar purposes, that each PAC provider has the opportunity to review and submit corrections to the data and information that are to be made public for the PAC provider prior to such data being made public.

Although assessment data submission, quarterly performance reports, and public reporting are required by statute, timing of data submission under the HH QRP is not specified. Thus, in the CY 2017 HHS PPS final rule (81 FR 76784) we finalized our proposal, to comply with the requirements of section 1899B(g) of the Act, that HHAs would have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, HHAs could review and perform corrections to errors in the assessment data used to calculate the measures.

In the process of implementing the public reporting programs, CMS has become concerned that the time between when data are collected and when the measures are reported from

those data may be too long to get the desired results in a public reporting program. Public reporting programs are designed to provide patients and their families with the most current information so they can make quality-informed decisions about where to receive their care. Currently, the largest contributing factor to the 9-month lag between end of the data collection and when measures are publicly reported is the current 4.5-month timeframe for data submission. If the timeframe for data submission was reduced from 4.5 months to 45 days, the lag time between collection and reporting could be reduced by up to 3 months. This would result in more timely public reporting that would be more valuable for patients and families as they make decisions about where they can receive the best care.

An important consideration in reducing the data submission timeframe is the potential burden it may place on providers, which could lead to lower quality data. CMS conducted analysis to evaluate the potential impact of reducing the timeframe by determining how many charts are being submitted by 60 days currently. Using 2022 data, CMS found that only 1.3 percent of all OASIS assessments were submitted after the 60-day timeframe. Of those submissions, only three-quarters (or 0.9 percent of the total) were submitted between 60 days and 4.5 months and hence have potential to be impacted. Because assessments are tied to payment, providers are likely to submit assessments close to the date of service and to close out medical records once the patient is discharged from service. Therefore, we believe that by reducing this deadline from 135 days to 45 days, we can reduce the time between data collection and public reporting resulting in the improvement in timeliness with limited change in burden to providers.

We are requesting feedback on this potential future reduction of the HH QRP data submission deadline from 4.5 months to 45 days. Specifically, we are requesting comment on the following:

- How this potential change could improve the timeliness and actionability of HH QRP quality measures.
- How this potential change could improve public display of quality information.
- How this potential change could impact HHA workflows or require updates to Systems.

We intend to use this input to inform our program improvement efforts.

K. Advancing Digital Quality Measurement in the HH QRP—Request for Information

As part of our effort to advance the digital quality measurement (dQM) transition, we are issuing this request for information (RFI) to gather broad public input on the dQM transition in HHAs.

1. Background

We are committed to improving healthcare quality through measurement, transparency, and public reporting of quality data, and to enhancing healthcare data exchange by promoting the adoption of interoperable health information technology (IT) that enables information exchange using Fast Healthcare Interoperability Resources® (FHIR®) standards. Proposing to require the use of such technology within the HH QRP in the future could potentially enable greater care coordination and information sharing, which is essential for delivering high-quality, efficient care and better outcomes at a lower cost. In the CYs 2022 and 2023 HH PPS proposed rules,¹⁷ we outlined several HHS initiatives aimed at promoting the adoption of interoperable health IT and facilitating nationwide health information exchange. Further, to inform our digital strategy, in the CY 2022 HH PPS proposed rule (86 FR 35980) we shared and sought feedback on the following:

- Our intent to explore the use of FHIR®-based standards to exchange clinical information through application programming interfaces (APIs).
- Enabling quality data submission to CMS through our internet Quality Improvement and Evaluation System (QIES).
- To work with healthcare standards organizations to ensure their standards support our assessment tools.

We are considering opportunities to advance FHIR®-based reporting of patient assessment data for the submission of the OASIS. Our objective is to explore how HHAs typically integrate technologies with varying complexity into existing systems and how this affects HH workflows. In this RFI, we seek to identify the challenges and/or opportunities that may arise during this integration, and determine the support needed to complete and submit quality data in ways that protect and enhance care delivery.

We are also seeking input on future measures under consideration including applicability of interoperability as a

¹⁷ “Advancing Health Information Exchange” in the CY 2022 HH PPS proposed rule (86 FR 35979) and CY 2023 HH PPS proposed rule (87 FR 37602).

future measure concept in post-acute care settings. We refer readers to section III.H.1. of this proposed rule for more information.

Any updates specific to the HH QRP program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

2. Solicitation of Comment

We seek feedback on the current state of health IT use, including electronic health records (EHRs), in HHAs:

- To what extent does your HHA use health IT systems to maintain and exchange patient records?
- If your agency has transitioned to using electronic records, in part or in whole, what types of health IT does your HHA use to maintain patient records? Are these health IT systems certified under the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program? If your agency uses health IT products or systems that are not certified under the ONC Health IT Certification Program, please specify. Does your agency use EHRs or other health IT products or systems that are not certified under the ONC Health IT Certification Program? If no, what is the reason for not doing so? Do these other systems exchange data using standards and implementation specifications adopted by HHS? Does your agency maintain any patient records outside of these electronic systems? If so, are the data organized in a structured format, using codes and recognized standards, that can be exchanged with other systems and providers?
- Does your HHA submit patient assessment data to CMS through your current health IT system? If a third-party intermediary is used to report data, what type of intermediary service is used? How does your agency currently exchange health information with other healthcare providers or systems, specifically between HHAs and other provider types? What about health information exchange with other entities, such as public health agencies? What challenges do you face with electronic exchange of health information?
- Are there any challenges with your current electronic devices (for example, tablets, smartphones, computers) that hinder your ability to achieve interoperability, such as collecting, storing, sharing, or submitting data? Please describe any specific issues you encounter. Does limited internet or lack of internet connectivity impact your ability to exchange data with other

healthcare providers, including community-based care services, or your ability to submit patient assessment data to CMS? Please specify.

- What steps does your HHA take with respect to the implementation of health IT systems to ensure compliance with security and patient privacy requirements such as HIPAA?
- Does your HHA refer to the Safety Assurance Factors for EHR Resilience (SAFER) Guides (see newly revised versions published in January 2025 at <https://www.healthit.gov/topic/safety/safer-guides>) to self-assess EHR safety practices?
- What challenges or barriers does your agency encounter when submitting quality measure data to CMS as part of the HH QRP? What opportunities or factors could improve your agency's successful data submission to CMS?
- What types of technical support, guidance, workforce trainings, and/or other resources would be most beneficial for the implementation of FHIR®-based technology in your agency for the submission of the OASIS to CMS? What strategies can CMS, HHS, or other Federal partners take to ensure that technical assistance is both comprehensive and user-friendly? How could Quality Improvement Organizations (QIOs) or other entities enhance this support?
- Is your agency using technology that utilizes APIs based on the FHIR® standard to enable electronic data sharing? If so, with whom are you sharing data using the FHIR® standard and for what purpose(s)? For example, have you used FHIR® APIs to share data with public health agencies? Does your agency use any Substitutable Medical Applications and Reusable Technologies (SMART) on FHIR® applications? If so, are the SMART on FHIR®¹⁸ applications integrated with your EHR or other health IT?
- How do you anticipate the adoption of technology using FHIR®-based APIs to facilitate the reporting of patient assessment data could impact provider workflows? What impact, if any, do you anticipate it will have on quality of care?
- Does your facility have any experience using technology that shares electronic health information using one or more versions of the United States Core Data for Interoperability (USCDI) standard?¹⁹
- Would your HHA and/or vendors be interested in participating in testing

¹⁸ <https://smarthealthit.org/>.

¹⁹ For more information about USCDI see <https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi>.

to explore options for transmission of assessments, for example testing the transmission of a FHIR®-based assessment to CMS?

- The Trusted Exchange Framework and Common Agreement™ (TEFCA™) framework supports nationwide health information exchange by connecting health information networks (HINs) across the country.²⁰ Additionally, TEFCA™ facilitates FHIR exchange by requiring Qualified HINs (QHINs) to perform patient discovery for those querying for data and providing data holders with FHIR endpoints to enable point-to-point exchange via FHIR APIs. How could the TEFCA™ support CMS quality programs' adoption of FHIR®-based assessment submissions consistent with the FHIR® Roadmap (available here: <https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/>)? How might patient assessment data hold secondary uses for treatment or other TEFCA™ exchange purposes?
- What other information should we consider that could facilitate successful adoption and integration of FHIR®-based technologies and standardized data for patient assessment instruments like the OASIS? We invite any feedback, suggestions, best practices, or success stories related to the implementation of these technologies.

While we would not be responding to specific comments in response to this RFI in the CY 2026 HH PPS final rule, we invite any feedback, suggestions, best practices, or success stories related to the implementation of these technologies and would use this input to inform our future dQM transition efforts.

L. Form, Manner, and Timing of Data Submission Under the HH QRP

We are not proposing any new policies regarding Form, Manner, and Timing of Data Submission Under the HH QRP in this proposed rule.

M. Policies Regarding Public Display of Measure Data for the HH QRP

1. Proposal To End the Public Display of Patient/Resident COVID-19 Measure

In the CY 2024 HH PPS final rule (88 FR 77762 through 77764), we finalized our proposal to begin publicly displaying data for the Patient/Resident COVID-19 measure beginning with the January 2026 Care Compare refresh. In section III.C.2, we are proposing to remove the Patient/Resident COVID-19 Measure beginning with the CY 2026

²⁰ For more information about TEFCA™, see <https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca>.

HH QRP. However, if finalized as proposed, effective with assessments completed on or after the date of publication of the CY 2026 HH final rule, the data from O0350 Patient's COVID-19 Vaccination is Up to Date may be submitted using any of the three valid responses (0—No, 1—Yes, or dash) on a Transfer, Death at home, or Discharge OASIS assessment, without any future quality measure implications.

We propose that the Patient/Resident COVID-19 measure rates would be publicly reported for the last time with the January 2026 Care Compare refresh on Medicare.gov, based on data from Q1 of 2025. We invite public comments on our proposal to end the public display of Patient/Resident COVID-19 Measure data after the January 2026 Care Compare refresh on Medicare.gov.

IV. The Expanded Home Health Value-Based Purchasing (HHVBP) Model

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the Center for Medicare and Medicaid Innovation (Innovation Center) implemented the Home Health Value-Based Purchasing (HHVBP) Model ("original Model") in nine states on January 1, 2016. The design of the original Model leveraged the successes and lessons learned from other CMS value-based purchasing programs and demonstrations to shift from volume-based payments to a model designed to promote the delivery of higher quality care to Medicare beneficiaries. The specific goals of the original Model were to—

- Provide higher incentives for better quality care with greater efficiency;
- Study new potential quality and efficiency measures for appropriateness in the home health setting; and
- Enhance the current public reporting process.

The original Model resulted in an average 4.6 percent improvement in HHAs' total performance scores (TPS) and an average annual savings of \$141 million to Medicare without evidence of adverse risks.²¹ The evaluation of the original Model also found reductions in unplanned acute care hospitalizations and skilled nursing facility (SNF) stays, resulting in reductions in inpatient and SNF spending. The U.S. Secretary of Health and Human Services (the Secretary) determined that expansion of the original Model will further reduce Medicare spending and improve the quality of care. In October 2020, the CMS Chief Actuary certified that

expansion of the HHVBP Model will produce Medicare savings if expanded to all states.²²

On January 8, 2021, CMS announced the certification of the HHVBP Model for expansion nationwide, as well as the intent to expand the Model through notice and comment rulemaking.²³ In the CY 2022 HH PPS final rule (86 FR 62292 through 62336), we finalized the decision to expand the HHVBP Model to all Medicare certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. CY 2022 was a pre-implementation year. The first payment year is CY 2025 based on the first performance year which was CY 2023. Our codified policies for the expanded HHVBP Model can be found in our regulations at 42 CFR part 484, subpart F, §§ 484.300 through 484.375.

In the CY 2024 HH PPS final rule (88 FR 77676), we finalized proposals to codify in the Code of Federal Regulations (CFR) the measure removal factors finalized in the CY 2022 HH PPS final rule; to replace the two Total Normalized Composite Measures (for Self-Care and Mobility) with the Discharge Function Score measure effective January 1, 2025; to replace the OASIS-based Discharge to Community (DTC) measure with the claims-based Discharge to Community-Post Acute Care (PAC) Measure for Home Health Agencies, effective January 1, 2025; to replace the claims-based Acute Care Hospitalization During the First 60 Days of Home Health Use and the Emergency Department Use without Hospitalization During the First 60 Days of Home Health measures with the claims-based Potentially Preventable Hospitalization measure effective January 1, 2025; to change the weights of individual measures due to the change in the total number of measures; and to update the Model baseline year to CY 2023 for all applicable measures in the finalized measure set beginning with performance year CY 2025.

B. Proposed Changes to HHVBP Measure Removal Factors

In the CY 2023 HH PPS final rule (88 FR 77776), CMS finalized the codification of specific factors that CMS considers for measure removal. Currently, there are eight measure removal factors that CMS considers when determining whether to remove measures from the expanded HHVBP

Model's applicable measure set. We are proposing to add and codify an additional measure removal factor at § 484.358, Factor 9: It is not feasible to implement the measure specifications.

This proposed new measure removal factor will enable CMS to address situations in which it is no longer feasible to continue implementing a quality measure, such as when a data collection instrument is revised in a way that no longer collects the information required for the quality measure specifications.

We invite public comments on this proposal.

C. Proposed Changes to the Expanded HHVBP Model's Applicable Measure Set

We are proposing to remove three measures from the current applicable measure set and add four measures starting in CY 2026. The removal of the three measures is necessary due to revisions to the HHCAHPS Survey that are proposed beginning with the April 2026 sample. These proposed survey revisions prevent the three HHCAHPS Survey-based measures from being calculated as currently specified. These measures will only be removed if the proposed changes to the HHCAHPS Survey are finalized.

1. Proposed Removal of Three HHCAHPS Survey-Based Measures From the Expanded HHVBP Model Applicable Measure Set

The Home Health Consumer Assessment of Healthcare Providers and System® (HHCAHPS) Survey, a nationally standardized and publicly reported survey, is designed to measure the experiences of people receiving home health care from Medicare-certified home health agencies. It is conducted for home health agencies by approved HHCAHPS Survey vendors. Currently, the expanded HHVBP Model includes five HHCAHPS Survey-based measures:

- Care of Patients
- Communications between Providers and Patients
- Specific Care Issues
- Overall Rating of Home Health Care
- Willingness to Recommend the Agency

The Care of Patients, Communications between Providers and Patients, and Specific Care Issues measures are based on multiple items from the HHCAHPS Survey while Overall Rating of Home Health Care and Willingness to Recommend the Agency are single-item measures.

Elsewhere in this proposed rule, the Center for Medicare (CM) is proposing

²² <https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvp-model.pdf>.

²³ <https://www.cms.gov/newsroom/press-releases/cms-takes-action-improve-home-health-care-seniors-announces-intent-expand-home-health-value-based>.

²¹ <https://innovation.cms.gov/data-and-reports/2020/hhvp-thirdann-rpt>.

changes to the HHCAHPS survey. These proposed changes will affect the survey questions used to calculate three measures that are used in the expanded HHVBP Model. CM plans to make changes to the questions used for two of the multi-item measures (Care of Patients and Communication between Providers and Patients). In addition, the Specific Care Issues measure will no longer exist as four of the seven items used for that measure will be removed from the survey. These changes are described in section III.H. of this proposed rule, and if finalized, will become effective in beginning with the April 2026 sample month.

Given these proposed changes, we propose to remove the following HHCAHPS Survey-based measures from the HHVBP applicable measure set starting with CY 2026:

- Care of Patients
- Communications between Providers and Patients
- Specific Care Issues

We propose to remove these three HHCAHPS Survey-based measures using the proposed Removal Factor 9: It is not feasible to implement the measure specifications. This proposed measure removal factor is described in more detail above. The proposed removal of these measures will be necessary if the proposed changes to the HHCAHPS Survey instrument are finalized, as the current measure specifications cannot be calculated using the proposed survey revisions. If the proposed changes to the HHCAHPS Survey instrument are finalized, several of the survey questions used to calculate the Care of Patients and Communication Between Providers and Patients measures will be changed and will no longer match the measure specifications. Also, four of the seven survey items used to calculate the Specific Care Issues measure would be removed if the survey changes are finalized, making it impossible to calculate the measure as currently specified.

While CMS could revise the HHCAHPS measures to use the proposed HHCAHPS Survey instrument changes, a full year of data with the revised HHCAHPS measures will not be available until CY 2027. Data from multiple quarters will be needed to establish benchmarks and achievement thresholds for the revised HHCAHPS Survey-based measures. Removing these three measures as part of this rulemaking cycle will give CMS the time needed to collect the required data and potentially develop updated benchmarks and achievement thresholds for revised or new measures.

If CMS decides to propose the addition of the new versions of the Care of Patients and Communications between Providers and Patients measures and individual item measures to replace the Specific Care Issues measure, CMS will do so through future rulemaking.

2. Proposed Addition of Medicare Spending Per Beneficiary Post-Acute Care (MSPB–PAC) to the Expanded HHVBP Model Applicable Measure Set

We propose to add the claims-based MSPB–PAC measure to the HHVBP applicable measure set starting in CY 2026. This cross-setting 2-year measure was required by the Improving Post-Acute Care Transformation Act of 2014 (IMPACT Act) and was added to the Home Health Quality Reporting Program on January 1, 2017.

Public comments on the CY 2025 HH PPS proposed rule (89 FR 88354) in support of adding this measure to the expanded HHVBP Model suggested that the MSPB–PAC measure could help to identify the costs associated with the delivery of high-quality home health services, which could identify areas for improved efficiencies in resource usage.

The MSPB–PAC measure is intended to incentivize providers to redesign care systems to provide coordinated, high-quality, and cost-efficient care. It holds HHAs accountable for Medicare payments for an episode of care that includes the period during which a patient is directly under HHA care, as well as a defined period after the end of HHA treatment, which may be reflective of and influenced by the services provided by the HHA. Evaluating Medicare payments during an episode creates a continuum of accountability between providers and has the potential to improve post-treatment care planning and coordination. In conjunction with the other performance measures used in the expanded HHVBP Model, explicit measurement of costs of care will allow recognition of HHAs that provide high quality care at a lower cost.

We anticipate that adding the MSPB–PAC measure will create incentives for greater care coordination to deliver high-quality care at a lower cost to Medicare and incentivize providers to find efficient ways to address patients' care needs. Incentivizing efficient resource utilization aligns with the pay-for-performance approach used in the expanded HHVBP Model. The MSPB–PAC measure would ensure that HHVBP payment adjustments consider not only patient outcomes but also HHA's ability to produce those outcomes at a lower cost.

The MSPB–PAC measure is a claims-based measure that includes price-standardized payments for Part A and Part B services. It measures Medicare spending during an episode of care relative to the Medicare spending for other home health agencies. The Medicare spending measure is payment standardized and risk adjusted. The MSPB–PAC measure captures Medicare spending for most Part A and B services during the episode of care, excluding services that are clinically unrelated to post-acute care treatment or services over which home health agencies may have limited to no influence (for example, routine management of certain preexisting chronic conditions). The episode of care window consists of a treatment period and an associated services period (from the admission to the home health services up to 30 days after the end of the home health treatment period). The episode includes the period a patient is directly under HHA care, as well as a defined period after the end of the HHA's treatment which may be reflective of and influenced by the services rendered by the HHA.²⁴

If this measure is finalized as proposed, we anticipate reporting preliminary benchmarks, achievement thresholds, and improvement thresholds for the MSPB–PAC measure in the October 2025 Interim Performance Reports (IPR). The MSPB–PAC measure will use 2 years of data covering CY 2022 and CY 2023 as baseline data. Because the MSPB–PAC measure is a two-year measure, CY 2026 performance for the measure will be calculated based on 2 years of performance data (CY 2025/2026). The MSPB–PAC measure was designed as a 2-year measure to optimize reliability. In addition, each performance year will consist of 1 year of data that does not overlap with data from the prior performance year, which provides sufficient opportunity to capture quality improvement over time.

Adding the MSPB–PAC and function measures described below will increase the number of HHAs that have sufficient data for at least five measures, the minimum required to have a payment adjustment for the expanded HHVBP Model. Increasing the number of HHAs that receive payment adjustments will allow the Model to better incentivize high-quality home health care across the country.

²⁴ See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/2016_07_20_mspb_pac_ltr_inf_snf_measure_specs.pdf for more details on the specifications for the MSPB–PAC measure.

3. Proposed Addition of OASIS-Based Function Measures to the Expanded HHVBP Model Applicable Measure Set

We propose adding three OASIS-based function measures to the HHVBP applicable measure set beginning with CY 2026:

- Improvement in Bathing (based on OASIS item M1830)
- Improvement in Upper Body Dressing (based on OASIS item M1810)
- Improvement in Lower Body Dressing (based on OASIS item M1820)

These measures are intended to complement the Discharge (DC) Function Score measure added to the HHVBP applicable measure set starting with CY 2025 to provide a more holistic picture of patients' functional status. The DC Function Score measure uses a cross-setting function item set which does not include items related to bathing or dressing.

These three measures have already been tested, validated, and implemented for other purposes within CMS models and programs. Improvement in Bathing is used in the Home Health Quality Reporting Program, the Home Health Quality of Patient Star Rating system, and reported on Care Compare. All three of the OASIS items underlying these measures were also used in the Total Normalized Change (TNC) in Self-Care measure that were part of the CY 2023 and CY 2024 expanded HHVBP Model applicable measure set. Additionally, the underlying OASIS M1800 items are used in the Home Health Patient-Driven Groupings Model that is used for Medicare home health payments. Therefore, adding these measures to the expanded HHVBP Model would align with existing quality measurement and payment practices. Adding these measures would not create additional burden to HHAs, as the data for these measures is already collected on OASIS assessments.

In the CY 2024 HH PPS final rule (88 FR 77676), CMS finalized the decision to add the DC Function Score measure to replace the previous OASIS-based TNC measures (TNC Self-Care and TNC Mobility). That change aligned the expanded HHVBP Model with other PAC quality programs. The DC Function Score measure is an OASIS-based measure that is used in the HH QRP and the expanded HHVBP Model starting in CY 2025. This measure reports the percentage of patients who meet or exceed an expected discharge function score during the reporting period. The DC Function Score measure considers two dimensions of patient function—

self-care and mobility activities—using 13 OASIS items.²⁵

The Model's Technical Expert Panel (TEP) has raised concerns that the DC Function Score measure does not consider bathing or dressing abilities, as these items are not available across all PAC settings covered by this cross-setting measure. TEP members identified the ability to bathe and dress as being critically important for home health patients. Many patients who receive home health care are recovering from an injury or illness and may have difficulty performing the tasks of bathing and dressing, requiring help from another person or special equipment to accomplish these activities. Improving patients' ability to bathe themselves contributes to patient comfort and quality of life and is often a rehabilitative goal for home health patients. These metrics also promote safer discharges from home care. Improvement in both upper and lower body dressing are important indicators of usefulness and improvement for patients, as well as indicators of being able to stay home, care for themselves, and be independent.

In 2024, TEP members supported CMS moving ahead as quickly as possible to add bathing and dressing function measures to the Model's applicable measure set to complement the DC Function measure. The TEP recommended using existing measures based on the OASIS M1800 items, which could be added sooner than future measures based on Section GG items.²⁶

The baseline data for these three measures will cover CY 2023, which was specified as the Model baseline year in the CY 2024 HH PPS final rule. This baseline data will be used to calculate benchmarks and achievement thresholds for the proposed OASIS-based function measures. If these three measures are finalized as proposed, we anticipate providing HHAs with the benchmarks, achievement thresholds, and improvement thresholds for the OASIS-based function measures in the October 2025 IPRs.

²⁵ These OASIS items and activities include GG0130 Self-Care, GG0130A Eating, GG0130B Oral hygiene, GG0130C Toileting hygiene, GG0170 Mobility, GG0170A Roll left and right, GG0170C Lying to sitting on side of bed, GG0170D Sit to stand, GG0170E Bed-to-chair transfer, GG0170F Toilet transfer, GG0170I Walk 10 feet, GG0170J Walk 50 feet with two turns, GG0170R Wheel 50 feet with two turns.

²⁶ The Section GG items were added to patient assessment tools for home health, skilled nursing facilities, inpatient rehabilitation facilities, and long-term care hospitals to support alignment of measurement of functional abilities and goals across post-acute care assessment instrument.

Adding these three measures would increase the number of OASIS-based measures used in the Model, allowing for more robust measurement of HHA performance. The change will also allow more HHAs to have sufficient data for at least five measures, the minimum required to calculate a payment adjustment. HHAs that receive payment adjustments will have greater incentives to improve or maintain quality of care.

4. Updates to Individual Measure Weights and Category Weights

Along with the proposed revisions to the current HHVBP applicable measure set, we propose to revise the weights of the individual measures starting with the CY 2026 performance year as well as to the measure category weights. Table 34 has current and proposed individual measure weights and category weights.

Changes to the measure weights are necessary given the proposed changes to the expanded HHVBP Model applicable measure set. Reflecting the reduction in the number of HHCAHPS Survey-based measures, the proposed weights include a lower total weight for the HHCAHPS Survey-based measures and a higher weight for the OASIS-based and claims-based measures. In addition, some of the weight for the current claims-based measures is shifted to the MSPB-PAC measure and some weight for the OASIS-based measures is shifted to the additional function measures. As with the current measure weights, higher weight is given to claims-based measures because they may have a greater impact on reducing Medicare expenditures. For example, HHAs with better performance scores on the claims-based PPH measure have lower rates of potentially preventable hospitalizations for their patients, reducing Medicare expenditures.

Currently, the OASIS-based, claims-based, and HHCAHPS Survey-based measures contribute 35 percent, 35 percent, and 30 percent, respectively, to the Total Performance Score (TPS) for HHAs in the larger-volume cohort. We propose adjusting the measure category weights for the larger-volume cohort such that the OASIS-based and claims-based measure categories each contribute 40 percent, and the HHCAHPS Survey-based measure category contributes 20 percent to the TPS due to the reduction in the number of individual HHCAHPS Survey-based measures. For HHAs in the smaller-volume cohort, the OASIS-based and claims-based measures both contribute 50 percent to the TPS. We do not propose changing the measure category weights for the smaller-volume cohort

as the HHCAHPS measures are not used for the smaller-volume cohort.

As proposed, changes to the applicable measure set would increase the number of OASIS-based measures from three measures to six and increase

the number of claims-based measures from two to three. The number of individual measures for the HHCAHPS Survey-based measures would decrease from five to two. Note that we have changed weights for measures and

measure categories in the past due to changes to the applicable measure set (for example, replacing the two TNC measures with the DC Function Score measure).

TABLE 34--CY 2025 AND PROPOSED INDIVIDUAL MEASURE WEIGHTS AND CATEGORY WEIGHTS FOR THE EXPANDED HHVBP MODEL

Measure	CY 2025 Measure Weights		Proposed Measure Weights	
	Larger-Volume Cohort	Smaller-Volume Cohort	Larger-Volume Cohort	Smaller-Volume Cohort
Improvement in Dyspnea	6.00%	8.57%	7.00%	8.75%
Improvement in Management of Oral Medications	9.00%	12.86%	11.00%	13.75%
Discharge Function Score (DC Function)	20.00%	28.57%	15.00%	18.75%
Improvement in Bathing	-	-	3.50%	4.38%
Improvement in Upper Body Dressing	-	-	1.75%	2.19%
Improvement in Lower Body Dressing	-	-	1.75%	2.19%
Sum of OASIS-based Measures	35.00%	50.00%	40.00%	50.00%
Home Health within-stay Potentially Preventable Hospitalization (PPH)	26.00%	37.14%	15.00%	18.75%
Discharge to Community – Post Acute Care (DTC-PAC)	9.00%	12.86%	15.00%	18.75%
Medicare Spending Per Beneficiary- Post-Acute Care (MSPB-PAC)	-	-	10.00%	12.50%
Sum of Claims-based measures	35.00%	50.00%	40.00%	50.00%
Care of Patients	6.00%	0.00%	-	-
Communication Between Providers and Patients	6.00%	0.00%	-	-
Specific Care Issues	6.00%	0.00%	-	-
Overall Rating of Home Health Care	6.00%	0.00%	10.00%	0.00%
Willingness to Recommend the Agency	6.00%	0.00%	10.00%	0.00%
Sum of HHCAHPS Survey-based measures	30.00%	0.00%	20.00%	0.00%
Sum of All Measures	100.00%	100.00%	100.00%	100.00%

5. Alternatives Considered

We considered two alternative options for revising the HHVBP measure weights prior to choosing the previously discussed proposals. Table 35 describes these alternative options for HHAs in the larger-volume cohort, including

maintaining measure category weights consistent with current measure set weights and adjusting within-category measure weights (Option 1), reducing the HHCAHPS-based measure category weight to 20 percent (Option 2), and maintaining HHCAHPS-based measure weights consistent with current measure

set weights, adjusting measure category weights accordingly (Option 3). We also considered these options for the smaller-volume cohort and came to the same conclusions. Therefore, we only provided a table with measure weighting alternatives for the larger-volume cohort.

TABLE 35 - ALTERNATIVE INDIVIDUAL MEASURE WEIGHTS AND CATEGORY WEIGHTS CONSIDERED FOR THE EXPANDED HHVBP MODEL

Measure	Option 1	Option 2	Option 3
	Maintain Category Weights	Reduce HHCAHPS Category Weight	Maintain Individual HHCAHPS Measure Weights
Improvement in Dyspnea	6.13%	7.00%	7.70%
Improvement in Management of Oral Medications	9.63%	11.00%	12.10%
Discharge Function Score (DC Function)	13.13%	15.00%	16.50%
Improvement in Bathing	3.06%	3.50%	3.85%
Improvement in Upper Body Dressing	1.53%	1.75%	1.93%
Improvement in Lower Body Dressing	1.53%	1.75%	1.93%
Sum of OASIS-based Measures	35.00%	40.00%	44.00%
Home Health within-stay Potentially Preventable Hospitalization (PPH)	18.00%	20.00%	16.50%
Discharge to Community – Post Acute Care (DTC-PAC)	8.50%	10.00%	16.50%
Medicare Spending Per Beneficiary- Post-Acute Care (MSPB-PAC)	8.50%	10.00%	11.00%
Sum of Claims-based measures	35.00%	40.00%	44.00%
Overall Rating of Home Health Care	15.00%	10.00%	6.00%
Willingness to Recommend the Agency	15.00%	10.00%	6.00%
Sum of HHCAHPS Survey-based measures	30.00%	20.00%	12.00%
Sum of All Measures	100.00%	100.00%	100.00%

We determined that these alternatives would be less consistent with previous decisions about applying differential weights to measures, and therefore these alternatives were not proposed.

We seek comments on these proposals.

D. HHVBP Quality Measure Concepts Under Consideration for Future Years—Request for Information

The expanded HHVBP Model provides an opportunity to examine a broad array of quality measures that address critical gaps in care. A comprehensive review of the Value-Based Purchasing (VBP) experience, conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), identified several objectives for HHVBP measures.²⁷ The recommended objectives emphasize measuring patient outcomes and functional status; appropriateness of care; and incentives for providers to build infrastructure to facilitate measurement within the quality framework. The study identified the following seven objectives which served as guiding principles for the development of performance measures used in the original Model:

- Use a broad measure set that captures the complexity of the HHA service provided.

- Incorporate the flexibility to include Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 measures that are cross-cutting amongst post-acute care settings.

- Develop second-generation measures of patient outcomes, health and functional status, shared decision making, and patient activation.
- Include a balance of process, outcome, and patient experience measures.
- Advance the ability to measure cost and value.
- Add measures for appropriateness or overuse.
- Promote infrastructure investments.

A central driver of the process used to select measures for the original Model was incorporating innovative thinking from the field while simultaneously drawing on evidence-based literature and documented best practices. Broadly, measures were selected based on their impact on care delivery and to support the goal of improving health outcomes, quality, safety, efficiency, and experience of care for patients.

As we continue to leverage our value-based purchasing initiatives to improve the quality of care furnished across healthcare settings, we are interested in considering new performance measures for inclusion in the expanded HHVBP Model. We specifically request public comments on one specific performance measure as well as general comments on other potential future model concepts that may be considered for inclusion in the expanded HHVBP Model. We encourage stakeholders to consider how

to reduce burden on HHVBP Model participants without compromising the quality of care when responding to the Deregulation RFI in the **SUPPLEMENTARY INFORMATION** section of this proposed rule.

1. Falls With Major Injury Measure (OASIS-Based and Claims-Based)

Within the home health population, approximately one third of individuals over the age of 65 experience one or more falls each year^{28 29}). Since 2022, CMS has reported rates for the Falls with Major Injury (FMI) measure on Care Compare. This measure is based on OASIS data.

A recent study³⁰ found that more than half of falls with a major injury (identified using Medicare claims data) were not reported on OASIS assessments. OIG observed that a low fall rate reported on Care Compare may

²⁸ Avin KG, Hanke TA, Kirk-Sanchez N, McDonough CM, Shubert TE, Hardage J, Hartley G; Academy of Geriatric Physical Therapy of the American Physical Therapy Association. Management of falls in community-dwelling older adults: clinical guidance statement from the Academy of Geriatric Physical Therapy of the American Physical Therapy Association. *Phys Ther.* 2015 Jun;95(6):815–34. doi: 10.2522/ptj.20140415. Epub 2015 Jan 8. PMID: 25573760; PMCID: PMC4757637.

²⁹ Carande-Kulis V, Stevens JA, Florence CS, Beattie BL, Arias I. A cost-benefit analysis of three older adult fall prevention interventions. *J Safety Res.* 2015 Feb;52:65–70. doi: 10.1016/j.jsr.2014.12.007. Epub 2015 Jan 6. PMID: 25662884; PMCID: PMC6604798.

³⁰ <https://oig.hhs.gov/reports/all/2023/home-health-agencies-failed-to-report-over-half-of-falls-with-major-injury-and-hospitalization-among-their-medicare-patients/>.

²⁷ U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2014). *Measuring Success in Health Care Value-Based Purchasing Programs*. Cheryl L. Damberg et al. on behalf of RAND Health.

reflect a provider's lack of falls reporting, rather than a low incidence of falls among its patients. OIG further observed that HHAs with low falls with major injury rates on Care Compare were more likely than other HHAs not to report falls among patients enrolled in Medicare. These findings raised concerns about the accuracy of this measure. In response to this OIG study, CMS is currently working on a respecified version of the FMI measure that uses fee-for-service claims, encounter data, and OASIS data. Using multiple data sources will produce a more robust and complete data set, allowing the respecified FMI measure to be more accurate and include more providers. Members of the Post-Acute Care (PAC) and Home Health Cross-Setting TEP also broadly agreed that data accuracy is vitally important for the measure's aim of making cross-provider comparisons.

In addition, the respecified FMI measure includes other injuries not explicitly covered in the OASIS-based FMI measure, which uses a specific measure of falls with major injury that includes only bone fractures, joint dislocations, closed head injuries with altered consciousness, and subdural hematomas.

We request comments related to the potential addition of the respecified FMI measure to the measure set for the expanded HHVBP Model.

2. Potential Future Changes to HHCAHPS Scoring Rules and Applicable Measure Set

We seek public comments regarding two potential changes to the HHCAHPS Survey-based measures scoring rules and applicable measure set as they relate to the expanded HHVBP Model:

a. Measuring HHA Performance on Forthcoming HHCAHPS Items Based Only on HHA Achievement

As discussed previously within this proposed rule, CMS anticipates proposing new HHCAHPS Survey-based measures to replace the Care of Patients, Communication Between Providers and Patients, and Specific Care Issues measures through future rulemaking. These revised HHCAHPS Survey-based measures will be based on data collected from the revised HHCAHPS Survey instrument. Data for these revised measures will be required to establish benchmarks and achievement thresholds. CMS will require 1 year of data to establish appropriate benchmarks and achievement thresholds for measuring HHAs' level of performance. By contrast, CMS will require 2 years of data to measure

improvement over time and establish improvement thresholds.

Therefore, CMS seeks public comments on the possibility of initially measuring HHA performance on the future HHCAHPS Survey-based measures based solely on achievement, rather than both achievement and improvement. This would allow CMS to potentially begin using the revised HHCAHPS measures in the expanded HHVBP Model starting with the CY 2028 performance year. If CMS proposes adding the achievement-based HHCAHPS Survey-based measures to the expanded HHVBP Model starting with the 2028 performance year, then benchmarks and achievement thresholds would be published in 2027, using data from 2026.

After sufficient data are available to develop appropriate improvement thresholds, CMS anticipates measuring HHA performance on these HHCAHPS Survey-based measures based on both achievement and improvement. This change would be proposed through future rulemaking.

b. Adding to the Applicable Measure Set for the Expanded HHVBP Model the Three Remaining Items in the Specific Care Issues Measure as Single Item Measures

As discussed previously, CM proposes to modify the HHCAHPS Survey instrument. Among other changes, this proposal would remove several items used in the multi-item Specific Care Issues measure. Three of the items used in the Specific Care Issues measure will remain in the HHCAHPS Survey instrument. The three items from the Specific Care Issues measure included in the revised HHCAHPS Survey instrument are as follows:

- When you first started getting home health care from this agency, did someone from the agency talk about ways to help make your home safer? For example, they may have suggested adding grab bars in the shower or removing tripping hazards.
- Has someone from the agency ever reviewed the prescribed and over-the-counter medicines you were taking? For example, they might have asked you to show them your medicines and talked with you about how and when to take each one.
- In the last 2 months of care, did home health staff from this agency talk with you about any side effects of your medicines?

CMS seeks public comments on the possibility of adding these three remaining HHCAHPS Survey items to the expanded HHVBP Model as single-

item measures. We also seek public comments on the possibility of giving each of these single item measures a weight of one third the weight of the other HHCAHPS items, thus maintaining the same relative weight of the Specific Care Issues measure.

V. Updates to the Home Health Agency Conditions of Participation (CoPs) To Align With the OASIS All-Payer Submission Requirements

A. Statutory Authority and Background

Section 1891(d) of the Act, cross-referencing section 1891(c)(2)(C)(i)(I) of the Act (section 4021(b) of Pub. L. 100–203 (December 22, 1987)) required the Secretary to develop a comprehensive assessment for Medicare-participating HHAs. In 1993, CMS (then known as Health Care Financing Administration (HCFA)) developed an assessment instrument that identified each patient's need for home care and the patient's medical, nursing, rehabilitative, social and discharge planning needs. As part of this assessment, Medicare-certified HHAs were required to use a standard core assessment data set, the Outcome and Assessment Information Set (OASIS). As part of the home health assessment, the statute requires a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care provided by the HHA. OASIS is the designated assessment instrument for use by an HHA in complying with the requirement and HHAs must submit the data collected by the OASIS assessment to CMS as an HHA CoP (42 CFR part 484.45).

Section 704 of the Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, December 12, 2003) “suspended” the legal authority of the Secretary to require HHAs to report non-Medicare and non-Medicaid patient data to CMS until at least two months after the Secretary published final regulations on CMS's collection and use of OASIS data following the submission of a report to Congress on the study required under section 704(c) of the MMA. Subsequently, CMS conducted the study from 2004 to 2005 and submitted a report to Congress in 2006 titled “The OASIS Study: The Costs and Benefits Associated with the Collection of Outcome and Assessment Information Set (OASIS) Data on Private Pay Home Health Patients—Report to Congress.” While the 2006 report recommended that the suspension continue, the passage of the Improving Medicare Post-Act Care Transformation

(IMPACT) Act (Pub. L. 113–115) in 2014 required CMS to create a uniform quality measurement system that allows CMS to compare outcomes across post-acute care (PAC) providers.

The final rule titled, “Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements” finalized the requirement for HHAs to report OASIS data on all patients, regardless of payer, for the applicable 12-month performance period (for example, July 1, 2025–June 30, 2026) (87 FR 66862). With the CY 2025 HH PPS final rule, CMS established that start of care (SOC) is the first assessment that can be submitted for a non-Medicare/non-Medicaid patient, either on or after January 1, 2025, for the phase-in (voluntary) period or on or after July 1, 2025, for the mandatory period. CMS will use the M0090 “Date Assessment Completed” date of the SOC assessment to identify non-Medicare/non-Medicaid patient assessments in the phase-in and mandatory periods (89 FR 88439 through 88441). This ended the suspension of the OASIS data collection on non-Medicare and non-Medicaid HHA patients. As discussed in the CY 2025 HH PPS final rule (89 FR 88439–88441), the most accurate representation of the quality of care furnished by HHAs is best captured by calculating the assessment-based measures rates using OASIS data submitted on all HHA patients receiving skilled care, regardless of payer.

B. Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements (§§ 484.45(a) and 484.55(d)(1)(i))

Section 484.45(a) of the HHA CoPs currently requires an HHA to encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each beneficiary with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary. To align with the transition to OASIS all-payer submission requirements as outlined in the CY 2023 HH PPS final rule (87 FR 66790), we are proposing at § 484.45(a) to remove the term “beneficiary” and replace it with the term “patient.” Thus, § 484.45(a) would state, if finalized as proposed, that an HHA must encode and electronically transmit each completed OASIS assessment to the

CMS system, regarding each patient with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the patient.

All patients must receive, and an HHA must provide, a comprehensive assessment no later than 5 calendar days after the start of care. The comprehensive assessment not only examines patients’ current health, psychosocial, functional, and cognitive status, but also must incorporate the most current version of the OASIS data items. This includes clinical record items, patient history, supportive assistance, etc. Currently, the comprehensive assessment, including administration of OASIS, must be updated and revised as frequently as the patient’s condition warrants, but not less frequently than the last 5 days of every 60 days beginning with the start-date of care. Language at § 484.55(d)(1)(i) describes a “beneficiary elected transfer” in reference to one scenario in which an OASIS assessment would be updated. To support the transition to OASIS all-payer submission requirements, we are also proposing to remove the term “beneficiary” at § 484.55(d)(1)(i).

These technical changes to update terminology would further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services and align the language in the CoPs with the requirements finalized in the CY 2023 and CY 2025 HH PPS final rules. These updates to the CoPs do not propose any revisions to the specific requirements for submitting data to OASIS and does not have any bearing on the change to expand the data collected that was finalized in the CY 2023 HH PPS final rule (87 FR 66862). We note that this policy does not change current patient exemptions for OASIS, which are as follows: patients under the age of 18; patients receiving maternity services; and patients receiving only personal care, housekeeping, or chore services.

VI. Provider Enrollment, Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Accreditation Policies, and DMEPOS Prior Authorization

A. Provider Enrollment

1. Medicare Enrollment

a. Background

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare

program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers (hereafter collectively “providers” unless otherwise noted) seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable Federal and State requirements to do so. The process is, to an extent, a “gatekeeper” that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to outline our enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.575 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one such requirement is that the provider must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS–855 (for example, the Form CMS–855A (OMB control number 0938–0685)). The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, PECOS), collects important information about the provider. Such data includes, but is not limited to, general identifying information (for instance, legal business name), licensure and/or certification data, and practice locations. The application is used for a variety of provider enrollment transactions, including all of the following:

- Initial enrollment—The provider is—(1) enrolling in Medicare for the first time; (2) enrolling in another Medicare contractor’s jurisdiction; or (3) seeking to enroll in Medicare after having previously been enrolled;

- Change of ownership—The provider is reporting a change in its ownership;

- Revalidation—The provider is revalidating its Medicare enrollment information in accordance with § 424.515. (Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) must revalidate their enrollment every 3 years; all other providers and suppliers must do so every 5 years.);

- Reactivation—The provider is seeking to reactivate its Medicare billing privileges after it was deactivated in accordance with § 424.540;

- Change of information—The provider is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving the provider's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider meets all applicable Medicare requirements. We believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse by keeping unqualified providers out of the Medicare program.

As previously mentioned, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers: (1) engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent with this, and as we discuss in this section VI.A.1.c of this proposed rule, we propose several changes to our existing Medicare provider enrollment regulations.

(We note that section VI.A.2 of this proposed rule addresses a proposed change to one of our Medicaid provider enrollment provisions.)

b. Legal Authorities

There are two principal categories of legal authorities for our proposed Medicare provider enrollment provisions:

- Section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers; and
- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

c. Medicare Provider Enrollment Provisions

(1) Revocation and Denial Reasons and Revisions to Other Revocation Policies

(a) Revocations and Denials

Under § 424.535(a), CMS may revoke a Medicare provider's enrollment for any of the reasons specified in that paragraph. These reasons include, for instance, the provider's: (i) failure to adhere to Medicare enrollment requirements; (ii) exclusion by the HHS Office of Inspector General (OIG); (iii)

felony conviction within the previous 10 years; (iv) pattern of improper or abusive billing; and (v) termination by another Federal health care program. A revocation is designed to safeguard the Medicare program, the Trust Funds, and beneficiaries by removing (and preventing payment to) Medicare providers that have engaged in problematic or otherwise non-compliant behavior. When a provider is revoked, it is generally barred from reenrolling in Medicare for a period of 1 to 10 years. The length of this "reenrollment bar" is determined based upon the severity of the basis of the revocation.

CMS also has numerous reasons in § 424.530(a) for which it can deny a provider's enrollment application, some of which duplicate our revocation grounds in § 424.535(a) (for instance, OIG exclusion, felony conviction, termination by another federal health care program). The general rationale for a denial is akin to that for a revocation: to protect the Medicare program and its beneficiaries from potentially fraudulent or abusive activity.

We have previously finalized a number of regulations adding new revocation and denial reasons to subpart P to address particular program integrity vulnerabilities and types of provider conduct. We have also used rulemaking to refine other policies regarding revocations, such as the effective dates of certain revocations. Given our continuing obligation to establish effective payment safeguards, we believe that several additions and revisions to our revocation and denial policies in subpart P are needed at this time.

(i) False or Misleading Information Revocation and Denial Ground (§§ 424.535(a)(4) and 424.530(a)(4))

Existing §§ 424.535(a)(4) and 424.530(a)(4) permit revocation or denial, respectively, if the provider or supplier certified as "true" misleading or false information on the enrollment application to be enrolled or maintain enrollment in Medicare. We propose to update § 424.510, which addresses certain general enrollment requirements, by adding new paragraph (d)(10). It would emphasize that all providers and suppliers are legally responsible for the accuracy, completeness, and truthfulness of all information they provide on or with their applications, regardless of whether another party completed the application. We have encountered situations where a provider has another individual complete an enrollment application on the provider's behalf (for example, officer manager). The

individual furnishes false or misleading information, and the provider (or, if applicable, the provider's authorized official) signs the application. The provider then later states it was not responsible for the submitted false data because the other person, not the provider, had furnished it. Such an assertion is incorrect. Our proposed revision would reiterate longstanding CMS policy that the enrolling provider bears ultimate legal responsibility for the accuracy and thoroughness of all data on the application. The provider cannot transfer this responsibility to another party even if the latter completed the application. To illustrate, the certification statement on the Form CMS-855I enrollment application (Medicare Enrollment Application—Physicians and Non-Physician Practitioners (NPP) (OMB control number 0938-1355)) requires the enrolling physician or NPP to attest and certify, under penalty of perjury, to meeting a number of Medicare requirements. These include, but are not limited to, that the physician or NPP—

- Has read the contents of the application, and that the information contained therein is true, correct, and complete;
- Has read and understands the Penalties for Falsifying Information, as printed in the application, and also understands that any omission, misrepresentation, or falsification of any information contained in the application or contained in any communication supplying information to Medicare may be punishable by criminal, civil, or administrative penalties; and
- Is indeed the physician or NPP applying for Medicare billing privileges and that the signature on the application is the physician's or NPP's.

Nothing in these attestations, nor anything in the enrollment applications or subpart P, indicates that a party other than the provider is responsible for the data in the application. It is, in the end, the provider's information, and the provider is certifying to its correctness, hence the reason for our proposed clarification.

(ii) Authority To Prescribe Drugs (§§ 424.535(a)(13)(ii) and 424.530(a)(11)(ii))

Sections 424.535(a)(13)(ii) and 424.530(a)(11)(ii) permit CMS to revoke or deny a physician's or eligible professional's enrollment if the licensing or administrative body for any state where the individual practices suspends or revokes the person's ability to prescribe drugs. We have received questions regarding the term "prescribe

drugs”—specifically, whether the state’s prohibition: (1) must be for all drugs for § 424.535(a)(13)(ii) or § 424.530(a)(11)(ii) to potentially apply; or (2) need only apply to one drug. Our position has long been the latter, and we accordingly propose to revise §§ 424.535(a)(13)(ii) and 424.530(a)(11)(ii) to change “prescribe drugs” to “prescribe one or more drugs.” Considering the seriousness of any state suspension or revocation action regarding an individual’s prescribing authority, we believe a prohibition involving even one drug is sufficient to warrant revocation or denial if we deem it necessary to protect beneficiaries and the Trust Funds.

(iii) Pattern or Practice of Prescribing (§ 424.535(a)(14))

We currently may revoke a physician’s or practitioner’s enrollment under § 424.535(a)(14) if the individual has a pattern or practice of prescribing Part B or D drugs that is abusive, threatens the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements. The purpose of this authority is to protect Medicare beneficiaries and the Trust Funds against harmful and non-compliant prescribing practices, and since the provision’s inception we have revoked the enrollments of a number of practitioners who have engaged in such conduct.

Drugs associated with services covered under Part A presently do not fall within the purview of § 424.535(a)(14). This is of increasing concern to us. Although Part A does not cover many drugs that beneficiaries take at home or in outpatient facilities, it can cover drugs administered as part of an inpatient covered stay, such as at a hospital or a skilled nursing facility. We do not believe the important protections that § 424.535(a)(14) affords must be dependent on the setting in which the drugs were furnished. That is, it is the abusive or non-compliant prescribing itself, rather than the beneficiary’s location or inpatient or outpatient status, that is most critical for purposes of program integrity. Beneficiaries can be endangered by such prescribing during inpatient stays no less than in other environments. For these reasons, we believe that only by expanding § 424.535(a)(14) to include drugs associated with Part A services can we be better able to address all instances of abusive Medicare prescribing—irrespective of the type of Medicare coverage or setting involved—to help shield beneficiaries and taxpayer monies from such conduct. We accordingly propose to revise

§ 424.535(a)(14) to change “Part B or D drugs” to “Medicare-covered drugs” to encompass Medicare Parts B, D, and now A.

(iv) Certain Modifications to Provider Enrollment Paragraph References (§§ 424.535(a)(23) and 424.530(a)(18)) and Enrollment Provisions (§ 424.205))

Sections 424.535(a)(23) and 424.530(a)(18) allow CMS to revoke or deny, respectively, a provider’s or supplier’s enrollment if the provider or supplier violates certain conditions and standards pertaining to its provider or supplier type. One such supplier type is Medicare Diabetes Prevention Programs (MDPP). Aforementioned paragraphs (a)(23) and (a)(18) state, in part, that revocation or denial is permissible if an MDPP violates an enrollment condition or standard in § 424.205(b) or (d), respectively. Although paragraphs (a)(23) and (a)(18) only apply to enrollment conditions and standards, § 424.205 (which was established in 2017) contains several other enrollment-related provisions, such as grounds for revocation. Yet we have not updated the enrollment requirements in § 424.205 post-2017, since which time: (1) paragraphs (a)(23) and (a)(18) were promulgated (in 2023); and (2) there have been revisions to the organizational structure of § 424.205. To ensure that (a)(23), (a)(18), and § 424.205 accurately reflect current policy and paragraph designations, we propose changes to all three.

First, the MDPP enrollment standards are now in § 424.205(c) rather than § 424.205(d). We accordingly propose that references to paragraph (d) would be changed to paragraph (c) in the following regulatory provisions:

- § 424.535(a)(23)(v).
- § 424.530(a)(18)(v).
- Definition of “Coach eligibility end date” in § 424.205(a) (reference to (d)(5) would change to (c)(5)).
- § 424.205(b)(4) (reference to (d)(5) would change to (c)(5)).
- § 424.205(b)(6).
- § 424.205(c)(3) (reference to (d)(5) would change to (c)(5)).
- § 424.205(c)(6) (reference to (d)(4) would change to (c)(4)).
- § 424.205(c)(8) (reference to (d)(8)(i) would change to (c)(8)(i)).
- § 424.205(c)(8)(ii) (references to (d)(8)(i)(B) and (d)(8)(i)(C) would change to (c)(8)(i)(B) and (c)(8)(i)(C), respectively).
- § 424.205(c)(10) (reference to (d)(8) would change to (c)(8)).
- § 424.205(c)(11)(iii).
- § 424.205(d)(2) (reference to (d)(5) would change to (c)(5)).
- § 424.205(g)(1)(ii).

- § 424.205(g)(1)(v)(A) (reference to (d)(3) would change to (c)(3)).

Second, the following references in § 424.205 would be revised to reflect that section’s present structure.

- In paragraph (c)(3), (e)(1) would change to (d)(1).
- In paragraph (c)(12), (g) would change to (f).
- In paragraph (c)(15), (g) would change to (f).
- In paragraph (d)(2), (e)(1) would change to (d)(1).
- In paragraphs (g)(1)(i)(A) and (B), (h)(1)(i) would change to (g)(1)(i).
- In paragraphs (g)(1)(ii)(A) and (B), (h)(1)(ii) would change to (g)(1)(ii).
- In paragraphs (g)(1)(v)(B) and (B)(2), (h)(1)(v) would change to (g)(1)(v).

Third, current § 424.205(g)(1)(i)(A) and (B) state that the MDPP supplier’s failure to meet the conditions in paragraph (b) is considered an enrollment denial or revocation, respectively, under §§ 424.530(a)(1) or 424.535(a)(1). Likewise, § 424.205(g)(1)(ii)(A) and (B) state that a failure to meet the standards in paragraph (d) is considered a denial or revocation, respectively, under §§ 424.530(a)(1) or 424.535(a)(1). We propose to add “or § 424.530(a)(18)” after paragraph references to § 424.530(a)(1) and “or § 424.535(a)(23)” after references to § 424.535(a)(1). This is because we can deny or revoke under either (a)(1) or (a)(18)/(23) in such situations. Our authority is not limited to (a)(1).

(v) Abuse of Billing Privileges (§ 424.535(a)(8)(i))

Section 424.535(a)(8) permits revocation based on the provider’s abuse of billing privileges. The latter term includes either of the following as outlined respectively in paragraphs (a)(8)(i) and (ii):

- The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service; and
- CMS determines that the provider has a pattern or practice of submitting claims that fail to meet Medicare requirements.

Paragraph (a)(8)(i) states that situations falling within its purview include but are limited to (and are enumerated as paragraphs (a)(8)(i)(A) through (C)):

- The beneficiary is deceased.
- The directing physician or beneficiary is not in the state or country when services were furnished.
- When the equipment necessary for testing is not present where the testing is stated to have occurred.

We propose to add new paragraph (i)(D) to § 424.535(a)(8) to include

another potential paragraph (a)(8) situation: specifically, the beneficiary attests that the item(s) or service(s) identified on the provider's or supplier's claim or claims was not or were not rendered or furnished. We have recently seen cases where providers have submitted claims for payment involving services or items that the beneficiary states were never provided. Although paragraph (a)(8)(i) has a "but are not limited to" caveat, meaning paragraphs (a)(8)(i)(A) through (C) are not exclusive, we believe the seriousness of the attestation cases we have seen and the potential fraud, waste, and abuse that has resulted therefrom warrant a specific mention of this situation in new paragraph (a)(8)(i)(D). This would make clear that § 424.535(a)(8)(i) applies to such cases.

(b) Retroactive Revocations Bases

Section 424.535(g) addresses revocation effective dates. Paragraph (g)(1) states that except as described in paragraphs (g)(2) and (g)(3), a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider. That is, the revocation effective date is prospective. However, paragraph (2) lists a number of situations where the revocation effective date is retroactive, meaning, generally, that the revocation becomes effective back to the date on which the provider's non-compliance with Medicare requirements commenced. To illustrate, paragraphs (g)(2)(ii) and (iii) outline the following retroactive revocation grounds and their corresponding effective dates:

- For revocations based on a felony conviction, the date of the felony conviction.
- For revocations based on a state license suspension or revocation, the date of the license suspension or revocation.

The aim of these and other exceptions in paragraph (g)(2) is to prevent payment to a provider while it is non-compliant. Assume a provider's license is revoked by the state on September 1. CMS learns of this and sends a revocation notice to the provider on September 15. If we applied paragraph (g)(1)'s prospective "30 days after mailing" timeframe, the provider could bill and be paid for services furnished between September 1 and October 15 while unlicensed, resulting in potentially thousands of dollars in improper Medicare payments. Preventing improper payments is a cornerstone of provider enrollment, and we believe that retroactive revocation effective dates are crucial means of ensuring that taxpayer monies are paid

only to legitimate, compliant providers. Indeed, it is for this reason that we added several new grounds for retroactive revocations (current paragraphs (g)(2)(v) through (viii)) in the Calendar Year (CY) 2024 Physician Fee Schedule (PFS) final rule (88 FR 78818).³¹ Yet because of our continuing serious concerns about improper payments to non-adherent providers and our responsibility to protect the Trust Funds, we propose to further expand the bases for which we can apply a retroactive revocation effective date. Our new grounds and effective dates, which would be designated as paragraphs (g)(2)(viii) through (xiv) (the requirement in current paragraph (g)(2)(viii) would be removed, as later explained), would respectively be as follows:

- For revocations based on a lapse in the IDTF's comprehensive liability insurance under § 410.33(g)(6), the date the insurance lapsed.
- For revocations based on the provider's or supplier's submission of false or misleading information on the enrollment application, the date the application's certification statement was signed.
- For revocations based on the provider's or supplier's failure to timely report a change of ownership or adverse legal action, or a change, addition, or deletion of a practice location, the day after the date by which the provider or supplier was required to report the change, addition, or deletion.
- For revocations based on the surrender of the provider's or supplier's Drug Enforcement Administration certificate of registration in response to a show cause order, the date the certificate was surrendered.
- For revocations based on the State's suspension or revocation of the physician's or practitioner's ability to prescribe one or more drugs, the date of the suspension or revocation.
- For revocations of any of the provider's or supplier's other enrollments under § 424.535(i), the effective date of the revocation that triggered the revocation(s) of the other enrollment(s).
- For revocations based on a DMEPOS supplier's non-compliance with a condition or standard in § 424.57(b) or (c), respectively, the date on which the non-compliance began.

In the foregoing situations, the provider or supplier has engaged in action or inaction resulting in non-compliance and/or otherwise concerning conduct. Regarding proposed paragraph (g)(2)(viii), lapsed IDTF liability insurance could have eliminated financial protection for beneficiaries negligently harmed by a test the IDTF performed. We believe such an insurance lapse and the risk it could have posed to patients warrants a retroactive revocation effective date. Moreover, because IDTF liability insurance is required per § 410.33(g)(6), failure to maintain it means the IDTF is non-compliant with enrollment requirements; the supplier must therefore not receive payments for services furnished on or after the date the non-compliance commenced. Providing false or misleading data on the enrollment application, meanwhile, in our view reflects dishonest behavior that could have resulted in improper payments to the provider. To illustrate, assume an enrolled provider had failed to report one of its practice locations on its application, knowing that it was not a valid site. If the provider furnished services from that site, it could have received payments to which it was not entitled due to the location's non-compliance. We believe the severity of such conduct justifies a retroactive revocation.

The same concerns about potential improper payments are behind proposed new paragraph (g)(2)(x). As an example, if a provider moves its practice location without notifying CMS and the new location does not meet the definition of "operational" in § 424.502, Medicare might have been paying for services while the provider was non-compliant with enrollment requirements. Accordingly, we believe this warrants application of the revocation retroactively to the date the non-compliance began as described in proposed paragraph (g)(2)(x). As for new paragraphs (g)(2)(xi) and (xii), meeting all applicable federal and state requirements is necessary for enrollment. If an individual is prescribing or dispensing drugs while non-compliant, we believe the risk this presented to beneficiaries after the loss of DEA or state authority justifies a revocation back to the date said loss occurred. With respect to proposed paragraph (g)(2)(xiii), we believe it would be inconsistent to apply one effective date to the triggering revocation and a different, later one to others, for the same individual or provider organization is involved in all these enrollments. Proposed paragraph

³¹ "Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program".

(g)(2)(xiv), in our view, is appropriate because the supplier's non-compliance may have resulted in payments (on or after the date of non-compliance) to which the supplier was not entitled.

We previously noted our authority under § 424.535(a)(8) to revoke a provider for the abusive billing situations described in paragraphs (a)(8)(i) and (ii). These situations are especially disconcerting with regard to the question of improper payments. If a provider is engaging in abusive billing, this, in our view, constitutes a direct threat to the Medicare program. To allow a provider that was revoked for submitting claims for unfurnished services to continue billing Medicare for another 30 days would run entirely counter to our role as steward of the Trust Funds. Consequently, we propose to include revocation bases in § 424.535(a)(8) as grounds for retroactive applicability.

New paragraph (a)(8)(iii) would state that the revocation effective date in paragraph (a)(8)(i) would be the earliest date of service on the claim or claims that are triggering the revocation. For instance, suppose CMS revokes the provider for submitting three claims for non-furnished services; the claims' service dates were June 1, June 5, and June 10. The revocation date would be the earliest of them, or June 1. Considering the serious program integrity risks associated with such claims, we do not believe the effective date must be the last claimed service date, for the risk commenced with the first claim's submission. The revocation effective date under paragraph (a)(8)(ii), meanwhile, would be the last date of service on the claims in question; using our prior example, this means the revocation effective date would be June 10. The reason for the different effective dates is that while paragraph (a)(8)(i) requires only one claim submission, paragraph (a)(8)(ii) requires a pattern or practice. . The last claim establishes the pattern or practice, hence the need to use the date thereon as the effective date.

To further accommodate new paragraph (a)(8)(iii), we would add reference to it in the previously noted opening clause of § 424.535(g)(1) as being excluded from application under paragraph (g)(1).

There are several other technical changes involving retroactive revocations we believe are necessary.

First, § 405.800(b)(2) states that a revocation is effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, the only exceptions being the revocations referenced in current

§ 424.535(g)(2)(i) through (iv), which are retroactive. Given our significant changes to § 424.535(g)(2) since promulgation of § 405.800(b)(2), we propose to replace the current language in the latter provision with a statement that the effective date of a revocation is as specified in § 424.535 (which would include § 424.535(a)(8)(iii) and (g)).

Second, § 424.57(e)(1) states that except as otherwise provided in § 424.57, a DMEPOS supplier's revocation for violating § 424.57(b) or (c) is effective 30 days after the entity is sent notice of the revocation, as specified in § 405.874. Similar to our proposed revision to § 405.800(b)(2), we propose to modify § 424.57(e)(1) to state that the revocation effective date would be as specified in § 424.535.

Third, current § 424.535(g)(2)(viii) outlines effective dates for revocations under § 424.535(a)(23). Paragraphs § 424.535(g)(2)(viii)(A) through (C) identify three situations where a retroactive effective date applies. Section 424.535(g)(2)(viii)(D), meanwhile, states that for all standard violations not addressed in paragraphs (A) through (C), the prospective effective date in paragraph (g)(1) applies if the effective date in paragraph (g)(3) does not. We propose two changes involving § 424.535(g)(2)(viii). One is that—given proposed new § 424.535(g)(2)(viii) through (xiv)—we propose to redesignate existing § 424.535(g)(2)(viii) as new § 424.535(g)(2)(xv). The other change would involve replacing the reference to “paragraphs (A) and (C)” in current § 424.535(g)(2)(viii)(D) (proposed new § 424.535(g)(2)(xv)(D)) with “paragraph (g)(2)”. This is because we are proposing to add certain standard violations to (g)(2) in paragraphs other than current (g)(2)(viii)(A), (B), and (C) (for example, including DMEPOS supplier standard violations in new § 424.535(g)(2)(xiv)).

(2) New Deactivation Authority

Regulatory policies regarding the provider enrollment concept of deactivation are addressed in § 424.540. Deactivation means that the provider's or supplier's billing privileges are stopped but can be restored (or “reactivated”) upon the submission of information required under § 424.540. While a deactivated provider or supplier is not revoked from Medicare, the provider's or supplier's ability to bill the program is halted pending its reactivation.

There are currently eight reasons under § 424.540(a) for which CMS can deactivate a provider or supplier, one of which is that the provider or supplier has not submitted any Medicare claims

for 6 consecutive months. In an April 25, 2003, proposed rule titled “Medicare Program; Requirements for Establishing and Maintaining Medicare Billing Privileges” (68 FR 22064) that proposed this non-billing deactivation ground, we outlined our program integrity concerns related to inactive billing numbers. We noted our desire to prevent dishonest parties from: (1) deliberately obtaining multiple numbers so they could keep one ‘in reserve’ [for future use] if their active billing number is subject to a payment suspension; and (2) obtaining information about discontinued providers or suppliers and then, for example, using the Medicare billing number of a deceased physician.³² Although we established a 12-month (rather than a 6-month) non-billing period in the subsequent final rule published in the **Federal Register** on April 21, 2006,³³ the need to shut down inactive billing numbers for the reasons noted previously persisted.

In the CY 2024 HH PPS final rule that appeared in the November 13, 2023, **Federal Register** (88 FR 77676), we reduced this 12-month period to 6 months.³⁴ We detailed our rationale for this change in the CY 2024 HH PPS proposed rule³⁵ by expounding upon the concerns we expressed in the aforementioned April 25, 2003, proposed rule. We cited an increasingly common example of a fraudulent, “whack-a-mole”-type scheme whereby a provider: (1) establishes multiple enrollments with multiple billing numbers; (2) abusively or inappropriately bills under one billing number; (3) receives an overpayment demand letter or becomes the subject of investigation; (4) voluntarily terminates the billing number in question; and then (5) begins to bill via another of its

³² Ibid. (68 FR 22072).

³³ “Medicare Program; Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment” (71 FR 20754).

³⁴ “Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements”.

³⁵ “Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements”. (88 FR 43654 (July 10, 2023)).

billing numbers that is dormant (for example, 6 consecutive months without billing) but nonetheless active, repeating the same improper conduct as before. We also further outlined the program integrity risks of extended non-billing periods, noting that in some cases the provider may have ceased operations without notifying CMS. Deactivating the provider's billing number enables CMS to not only prevent it from being accessed by other parties but also confirm via the deactivation process whether the provider or supplier is in fact operational—specifically, whether the provider responds with a reactivation application. In other words, action under § 424.540(a)(1) helps protect the Medicare program by deactivating the number while enabling verification as to whether the provider remains in existence; if it does, and it subsequently submits a reactivation application, CMS can validate the data thereon to ensure the provider's continued credentials and compliance with Medicare requirements.

We recognize that the deactivation concept has only applied to Medicare billing privileges rather than the ordering, certifying, and referring (OCR) of Medicare services and items. Yet this does not mean improper OCR poses a significantly less risk to the Medicare program and its beneficiaries than billing for Medicare services. To the contrary, we have established a number of provider enrollment requirements to prevent inappropriate OCR. Several examples follow.

First, under § 424.507(a) and (b), physicians and practitioners who wish to order or certify certain Medicare services and items must either opt-out of Medicare (pursuant to 42 CFR part 405, subpart D) or enroll in Medicare. Even if the individual does not seek to bill Medicare and only wants to order or certify the services and items addressed in § 424.507, the person must still enroll in Medicare by submitting a Form CMS–855O application (Medicare Enrollment Application—Registration for Eligible Ordering and Referring Physicians and Non-Physician Practitioners (OMB control number. 0938–1135)). Though a shorter, more abbreviated form than other CMS–855 applications, the Form CMS–855O requires the individual to furnish important information regarding, for instance, licensure and final adverse actions. This enables CMS to screen the person to ensure that all Medicare requirements are met, hence reducing the payment safeguard risk that an unvetted physician or practitioner intent on fraudulent or abusive conduct can order or certify such services or items.

Second, pursuant to § 424.535(a)(21) we may revoke a physician's or eligible professional's enrollment if the individual has a pattern or practice of ordering, certifying, or referring Medicare Part A or B services or items that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements. This provision was established in response to instances of fraudulent or unnecessary ordering, certifying, and referring of Medicare services and items, which resulted in: (1) Medicare payment for services or items that beneficiaries did not require; and (2) potential harm to beneficiaries from these unnecessary services or items. We also believed the potential for revocation would deter physicians and other eligible professionals from engaging in such activity, thus reducing fraud and waste and enhancing beneficiary safety.

Third, under § 424.542(a) a physician or other eligible professional who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests Medicare and its beneficiaries may not order, refer, or certify Medicare services or items. As with § 424.535(a)(21), the aim of § 424.542(a) is to prevent fraud, abuse, and beneficiary harm.

All the foregoing signifies that CMS takes improper and abusive ordering, referring, and certifying no less seriously than improper and abusive billing. The former can be just as harmful to Medicare and its beneficiaries as the latter. For this reason, we do not believe that important program integrity safeguards such as deactivation must be limited to billing situations. A Form CMS–855O-enrolled physician or practitioner's unused ordering, certifying, or referring number (which CMS assigns to the individual upon enrollment) can be accessed by nefarious parties to the same extent as an unused billing number. Our obligation to protect beneficiaries and the Trust Funds, in our view, requires us to prevent such improper access, and we accordingly propose to do so in new § 424.547.

In § 424.547(a)(1)(i) and (ii), respectively, we propose that CMS may deactivate a physician's or non-physician practitioner's ability to order, certify, or refer the Medicare services or items described in § 424.507(a) and (b) if the individual:

- Is enrolled via the Form CMS–855O application solely to order, certify, or refer Medicare services or items; and
- Has not been listed as the ordering, certifying, or referring individual on a

Medicare Part A or B claim received in the previous 12 consecutive months.

We are comfortable with initially establishing a 12-month period. This would be consistent with the 12-month timeframe we originally established in 2006 for § 424.540. Should we determine after implementation that a shorter timeframe is warranted, we may consider future rulemaking.

To distinguish deactivations of billing privileges from those of ordering, referring, or certifying capabilities, we propose in new § 424.547(a)(2) that for purposes of § 424.547 only, the term “deactivate” means that the physician's or non-physician practitioner's ability to order, certify, or refer Medicare services or items has been stopped but can be restored upon the submission of updated information. In a similar vein, because the current definition of deactivation in § 424.502 is limited to billing privileges, we propose to add the following language to the beginning of this definition: “Except in the situations described in § 424.547”. We also believe that some of the deactivation and reactivation procedures and impacts in § 424.540 must be included within new § 424.547. These have existed for numerous years and help us obtain updated information on non-billing providers to ensure the latter are still active and have not, for instance, ceased operations. We thus propose the following, which would mirror, respectively, current § 424.540(b)(1), (b)(2), (d)(2), and (e):

- In § 424.547(b)(1), we would state that for a deactivated physician or practitioner to reactivate their ability to order, certify, or refer Medicare services and items, the individual must recertify that their enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in Title 42.

- In § 424.547(b)(2), we would state that notwithstanding § 424.547(b)(1), CMS may, for any reason, require a deactivated physician or practitioner to, as a prerequisite for reactivating the ability to order, certify, or refer, submit a complete Form CMS–855O application.

- In § 424.547(c), we would state that the effective date of a reactivation of the ability to order, certify, or refer Medicare services and items under § 424.547 is the date on which the Medicare contractor received the individual's reactivation submission that was processed to approval.

- In § 424.547(d), we would clarify that a physician or practitioner may not order, certify, or refer the Medicare

services or items referenced in § 424.507(a) and (b) while deactivated under § 424.547.

(c) Revisions to Stay of Enrollment Authority (§ 424.541)

As already noted, revocations and deactivations are two important vehicles CMS uses to prevent Medicare fraud, waste, and abuse as well as improper payments. In the CY 2024 PFS final rule, we promulgated a third vehicle labeled a stay of enrollment, which is addressed in § 424.541. Under § 424.541(a)(1) and (2), we can impose a stay of enrollment against a provider if the latter:

- Is non-compliant with at least one enrollment requirement in Title 42; and
- Can remedy the non-compliance by submitting, as applicable to the situation, a Form CMS-855, Form CMS-20134, or Form CMS-588 change of information or revalidation application.

We established the stay of enrollment concept based largely on our concern that there were instances of provider non-compliance that did not necessarily warrant a measure as significant as a deactivation, much less a revocation. We believed that a more moderate CMS approach in addressing such cases would ease the burden on such providers without hindering our obligation to protect the Trust Funds. In further explaining our rationale for the stay of enrollment, we outlined in the CY 2024 PFS final rule several critical differences between this new action and revocations and deactivations.

The first involves the length of the action. We previously noted that a revoked provider is subject to a reenrollment bar typically lasting between 1 to 10 years. Deactivations last until the provider has reactivated its billing privileges under § 424.540; if no reactivation occurs, the deactivation remains effective indefinitely. A stay of enrollment, however, lasts a maximum of 60 calendar days, during which period the provider remains enrolled in Medicare, unlike with a revocation. Described otherwise, a stay of enrollment represents a comparatively brief “pause” in the provider’s enrollment that permits the provider to quickly resume compliance without the greater burdens associated with deactivations and revocations.

The second pertains to payments. Section 424.541(a)(2)(ii)(A) states that claims submitted by the provider with dates of service within the stay period will be rejected. However, there is a critical caveat. Under § 424.541(a)(2)(ii)(B), claims submitted by the aforementioned provider in this situation are, in fact, eligible for

payment (and may be resubmitted by the provider within applicable timeframes specified in Title 42) if—

- CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42; and
- The stay ends on or before the 60th day of the stay period.

This means that whereas revocations and deactivations prohibit payment for services or items furnished during the revocation or deactivation period with no possibility of retroactive payments, a stay of enrollment permits the latter if the requirements of § 424.541(a)(2)(ii)(B) are met.

A third involves the timing and mechanism for how the provider can resume compliance. A revoked or deactivated provider cannot, respectively, re-enroll in Medicare (after the reenrollment bar expires) or reactivate its billing privileges until the applicable provider enrollment application process is complete, which can take considerable time. Under § 424.541(a)(5), a stay of enrollment can end on the date on which CMS or its contractor determines that the provider has resumed compliance with all Medicare enrollment requirements in Title 42. However, for purposes of § 424.541(a)(5) only, we have interpreted the term “has resumed compliance” as meaning the provider has submitted the required application referenced § 424.541(a)(1)(ii) (for example, Form CMS-855 change of information). With this, a stay could end within a few days, allowing the provider to rapidly resume billing.

Considering the burden-reducing aspects of the stay concept, we believe its scope must be expanded to cover other situations. While this proposed rule has focused largely on preventing improper payments, we also believe that providers must not be excessively or unfairly penalized for minor instances of non-compliance that, in general, do not pose or potentially pose significant threats to the Medicare program. One such situation is where a provider submits a revalidation or change of information application that is rejected under § 424.525(a)(1) or (2). Per these provisions, rejection is permissible if the provider does not furnish complete information on the application (or required supporting documentation under (a)(2)) within 30 calendar days of the date the Medicare contractor requested the missing or incomplete data or documentation. A deactivation often follows the rejection. Unlike cases where the provider did not submit the required revalidation or change of

information at all, the provider in § 424.525(a)(1) cases did submit the application, albeit incompletely. Accordingly, we do not believe the latter situations must be treated more harshly via a deactivation than the former. It would be inconsistent to allow the more concerning action of application non-submission to be subject to a stay and not situations where the provider actually submitted the form. To this end, and to further the goal of reducing provider burden, we propose to expand § 424.541(a)(1)(i) to include instances where the provider’s change of information or revalidation application is rejected under § 424.525(a)(1) or (2)).

In addition, current § 424.541(a)(3) states that a stay of enrollment lasts no longer than 60 days from the postmark date of the notification letter, which is the effective date of the stay. We believe two changes to this section are necessary.

First, we propose to delete existing § 424.541(a)(3) and, in new § 424.541(a)(3)(i), state that the effective date of a stay is, as applicable: (1) the date on which the provider’s or supplier’s non-compliance began; or (2) the date on which the provider’s or supplier’s change of information or revalidation application was rejected under § 424.525. In light of our concerns about payments to providers when they are non-compliant, we no longer believe commencing the stay period upon the notification letter’s postmark date is appropriate. As an illustration, assume a provider became non-compliant on June 1 and the stay notice was postmarked on June 6. This means that the provider’s claims for a 5-day period (June 1 to 6) can be paid even though the provider is non-compliant. With our proposed change, however, these claims would be rejected due to the stay’s June 1 effective date. We believe the latter is a better approach for preventing payments to non-compliant providers.

Second, we propose in new § 424.541(a)(3)(ii) that CMS may establish a stay of enrollment for any period up to a maximum of 60 days. This is consistent with current CMS policy, but we wish to make clearer that the CMS-assigned stay period need not be 60 days but can be any timeframe up to that point.

We previously noted the reference in § 424.541(a)(2)(ii)(B) regarding claim submission eligibility, with § 424.541(a)(2)(ii)(B)(2) referencing the end of the stay on or before the 60th day. We propose to revise paragraph (a)(2)(ii)(B)(2) to replace the 60-day reference therein with the requirement that the stay must end on or before the

expiration of the originally designated stay period. This would further clarify that the stay period can be less than 60 days. Meanwhile, § 424.541(a)(5) states that a stay of enrollment ends on the date on which CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42 or the day after the 60-day stay period expires, whichever occurs first. Since the stay period CMS has assigned may be less than 60 days, we propose to change “60-day period” to “CMS-assigned stay period”.

(d) Submission of Documentation

One of the many critical functions of MACs is to validate the accuracy of the information the provider furnishes on its enrollment application. If submitted data is incorrect, the potential exists for improper payments based thereon. Consider the following: (1) an individual practitioner indicates on the application that all licensure and certification requirements have been met; and (2) a provider lists a particular address as its practice location. If these providers’ respective applications were approved without verifying these data elements and it turns out the individual did not, in fact, meet licensure and certification requirements or had an invalid practice location, many thousands of dollars could be inappropriately paid to providers that did not meet Medicare requirements. Although MACs can validate certain data via electronic means, verifying documentation from the provider is sometimes needed. Sections 424.510(d)(2)(ii), (iii)(A), and (iii)(B) therefore state that each submitted provider enrollment application must include the following:

- Documentation to identify the provider, such as proof of the legal business name, practice location, social security number, tax identification number (TIN), National Provider Identifier, and the business’ owners.
- All applicable Federal and State licenses and certifications including, but not limited to, Federal Aviation Administration; and
- Documentation associated with regulatory and statutory requirements needed to establish a provider’s eligibility to furnish Medicare covered items or services.

Some of this documentation is also identified on the Form CMS–855 enrollment applications as materials the provider must submit with its application. These include, for example, proof of licensure, sales agreements for ownership changes, and Internal

Revenue Service documentation of the provider’s TIN.

Notwithstanding existing § 424.510 and the documents that providers must currently submit, we remain concerned about the MACs’ ability to verify all information on the applications they receive. This is especially true regarding the provider’s ownership and management. Consistent with sections 1124 and 1124A of the Act, providers must report this data on their enrollment applications. Inaccurate ownership and managerial information, like other reported data, could result in improper payments. To illustrate, suppose a provider has five owners it must report but only discloses four. The fifth one was not listed because that owner is excluded by the OIG. If this provider is subsequently enrolled because of an inability to verify (1) the provider’s current ownership and that (2) all owners are reported, we would be paying a provider with an excluded owner in violation of federal law.

To therefore strengthen our ability to validate ownership and managerial data—as well as other information that CMS or the MAC may be unable to verify through current means—we propose in new § 424.510(d)(2)(iii)(C) that CMS may require the submission of any other documentation needed to verify and confirm the information furnished on the enrollment application; this includes, but is not limited to, documentation regarding the provider’s or supplier’s ownership or management. We emphasize that our proposal does not necessarily mean that the amount of documentation providers must currently submit will greatly increase. It only means CMS reserves the right to request validating documents if needed to ensure the accuracy of the provider’s information.

(e) Reassignment Effective Dates

In the provider enrollment context, and consistent with 42 CFR 424.80, reassignment of benefits refers to the scenario in which an individual physician or non-physician practitioner has granted another Medicare-enrolled provider or supplier the right to receive payment for the physician’s or non-physician practitioner’s services. Existing § 424.522(a) states that a reassignment is effective beginning 30 days before the Form CMS–855R (OMB control number 0938–1179) is submitted if all applicable requirements during that period were otherwise met. The CMS–855R (Medicare Enrollment Application for Reassignment of Medicare Benefits) was long used by physicians and practitioners to reassign their right to Medicare payment to

another party and for the latter to accept such reassignment. However, with the Form CMS–855R now obsolete and the collection of reassignment information currently facilitated via the Form CMS–855I (OMB control number 0938–1355) and Form CMS–855B (OMB control number 0938–1377) applications, we must revise § 424.522(a) to reflect both the elimination of the Form CMS–855R and the need to establish a new reassignment effective date.

Under current § 424.520(d)(1)(i) and (ii), the effective date of billing privileges for physicians and non-physician practitioners is the later of—

- The date of filing of a Medicare enrollment application that a MAC subsequently approved; or
- The date the individual first began furnishing services at a new practice location.

Notwithstanding § 424.520(d)(1), physicians and non-physician practitioners under § 424.521(a)(1) may retroactively bill for services when they have met all program requirements and services were provided at the practice location for up to—

- 30 days before their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- 90 days before their effective date if a Presidentially declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5206 (Stafford Act) precluded enrollment in advance of furnishing services to Medicare beneficiaries.

Because reassignments are often initiated at the same time a physician or practitioner enrolls in Medicare via the Form CMS–855I, we believe the effective dates of the two (that is, the initial enrollment and the reassignment) should be determined in the same manner, especially since, as noted, reassignments are now captured via the Form CMS–855I. In our view, it would be confusing to physicians, practitioners, and other stakeholders to have different regulatory effective dates for two separate transactions reported on the same form. Therefore, we propose to modify § 424.522(a) such that the reassignment’s effective date and the ability to retroactively bill for services mirror the provisions in § 424.520(d)(1) and 424.521(a)(1). Specifically, new § 424.522(a)(1) would state that the reassignment’s effective date is the later of the two dates identified in § 424.520(d)(1)(i) and (ii). New § 424.522(a)(2) would state that retrospective billing pursuant to a reassignment is permissible if the circumstances in § 424.521(a)(1) apply.

(f) DMEPOS Liability Insurance

Section 424.57(c) outlines a number of standards that DMEPOS suppliers must meet to become or remained enrolled in Medicare. One such standard, codified in § 424.57(c)(10), requires the supplier to have a comprehensive liability insurance policy of at least \$300,000 that covers the supplier's place of business, customers, and employees. We have seen instances where the insurance policy is signed by a supplier employee who did not appear to have the authority to act on the supplier's behalf. Considering the importance of the liability insurance requirement, we must ensure that the supplier, through its signature on the policy, is bound by its terms. Accordingly, we propose to modify § 424.57(c)(10) such that an "authorized official" of the supplier (as that term is defined in § 424.502) must sign the liability insurance policy.

(g) Deactivation Reason Clarification

Section 424.550(b) addresses "change(s) in majority ownership" (CIMO) (as that term is defined in § 424.502) involving home health agencies (HHA) and hospices. Unless an exception applies, an HHA or hospice undergoing a CIMO must enroll in Medicare as a new HHA or hospice and undergo a state survey or accreditation. Since, in this situation, the seller will be departing the Medicare program, § 424.540(a)(8) permits CMS to deactivate the seller's billing privileges. However, § 424.540(a)(8) currently only references sellers in an HHA CIMO and not those in a hospice CIMO. As a technical clarification, we thus propose to include the latter within the scope of § 424.540(a)(8).

(h) Adverse Legal Actions

Consistent with § 424.516(b) through (d), certain provider and supplier types—such as physicians, non-physician practitioners, DMEPOS suppliers, and independent diagnostic testing facilities—must report any adverse actions (for example, felony convictions, misdemeanor conviction related to health care, medical license revocation) imposed against them, their owners, managing employees or organizations, or corporate directors or officers within 30 calendar days of the action. Other provider and supplier types, however, have 90 days to report this information. Existing § 424.516(e)(1) states that for all provider and supplier types other than those in § 424.516(b) through (d) (as well as MDPPs), changes of ownership or control and practice location changes,

additions, and deletions must be reported within 30 days. We propose to include adverse legal actions within § 424.516(e)(1), meaning all providers and suppliers, regardless of type, would have 30 days, rather than 90 in some instances, to disclose this data. We believe this would establish more consistent reporting timeframes. More importantly, a 30-day requirement would alert us much sooner when the provider or an associated party poses a risk of fraud, waste, or abuse or and better allow us to take corresponding measures to protect the Medicare Trust Funds and Medicare beneficiaries.

2. Medicaid and CHIP Enrollment and Termination

The Medicaid program (title XIX of the Act) is a joint Federal and State health care program that (as of October 2024) covers more than 72 million low-income individuals. States have considerable flexibility when administering their Medicaid programs within a broad Federal framework, and programs vary from State to State. The Children's Health Insurance Program (CHIP) (title XXI of the Act) is a joint Federal and State health care program that (as of October 2024) provides health care coverage to over 7 million children in families with incomes too high to qualify for Medicaid, but too low to afford private coverage.

In operating Medicaid and CHIP, and as required by sections 1902(a)(78) and 2107(e)(1)(D) of the Act, respectively, each State requires providers to enroll in order to furnish, order, prescribe, refer, or certify eligibility for Medicaid or CHIP items or services in that State.³⁶ States may also establish their own provider enrollment requirements which must be met in addition to the applicable Federal provider enrollment requirements. Similar to Medicare provider enrollment, the purpose of the Medicaid and CHIP provider enrollment processes is to ensure that providers: (1) meet all Medicaid or CHIP requirements (and any other State-specific or Federal requirements); (2) are qualified to furnish, order, prescribe, refer, or certify Medicaid and CHIP services, items, and drugs; and (3) are eligible to receive payment, where applicable.

Different States may have different provider enrollment processes in operating their Medicaid and CHIP programs. However, all States must comply with Federal Medicaid and

CHIP provider enrollment statutory and regulatory requirements, including those in part 455, subparts B and E.³⁷ One such requirement, outlined in section 1902(a)(39) of the Act and which will be the subject of this section VI.A.2. of this proposed rule, is that the State must deny or terminate a provider's Medicaid or CHIP enrollment if the provider is—

- Terminated under the Medicare program, or the Medicaid program or CHIP of any other State; and
- Currently included in the termination database under § 455.417.

CMS established this termination database pursuant to sections 1902(kk)(8) and 1902(ll) of the Act. These two sections are summarized as follows:

- Require the State to report the termination of a provider under Medicaid or CHIP to the Secretary within 30 days after the effective date of the termination. However, this reporting requirement is limited to terminations for reasons specified in § 455.101, which, in turn, are restricted to terminations "for cause" (including, but not limited to, terminations for reasons relating to fraud, integrity, or quality);

- Provide that within 30 days of receiving notification of a Medicaid or CHIP provider termination, the Secretary must review such termination and, if the Secretary determines appropriate, include such termination in any database or similar system developed under section 6401(b)(2) of the Affordable Care Act.

CMS has developed and currently operates such a database. It contains information on Medicaid and CHIP terminations and Medicare revocations. It enables a State to: (1) review Medicaid and CHIP terminations in other States, as well as Medicare revocations; and (2) to deny enrollment under § 455.416(c) or take its own termination action against a provider if the latter is also enrolled in the State.

The previously referenced provisions of section 1902(a)(39) of the Act are currently incorporated in § 455.416(c), though with one inadvertent exception. Rather than stating that the provider—along with being in the termination database—must be terminated under the Medicare program or the Medicaid program or CHIP of any other State, § 455.416(c) states that the provider's termination must be from Medicare and the Medicaid or CHIP program of any state. That is, the word "and" is between the references to Medicare and

³⁶ Section 1902(kk)(7) of the Act also requires physicians and other eligible professionals who order or refer Medicaid services and items to be enrolled in Medicaid. This requirement is made applicable to CHIP via section 2107(e)(1)(G) of the Act.

³⁷ All of subpart E, and 42 CFR 455.107 in Subpart B, are applicable to CHIP in accordance with § 457.990.

Medicaid when the word “or” should be there instead, consistent with the statutory language. To correct this issue and to ensure compliance with section 1902(a)(39) of the Act, we proposing to change the aforementioned “and” reference to “or.”

B. DMEPOS Supplier Accreditation Process

1. Introduction

a. Overview of DMEPOS Accreditation

(1) DMEPOS Suppliers

(A) Background

Among the types of providers and suppliers that must enroll in Medicare to bill the Medicare program are DMEPOS suppliers. Such suppliers include, but are not limited to, the following:

- Medical supply companies that exclusively furnish DME like wheelchairs, walkers, and canes.
- Physicians and non-physician practitioners who provide DMEPOS to their own patients.
- Home health agencies (HHAs) and hospitals that provide DMEPOS to their own patients
- Oxygen and oxygen equipment suppliers.
- Prosthetists and orthotists.
- Pharmacies.

DMEPOS suppliers enroll in Medicare via the Form CMS–855S application (Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); OMB Control No. 0938–1056). Per 42 CFR 424.57(b)(1)—and excluding locations it utilizes solely as warehouses or repair facilities—the supplier must separately enroll each physical location it uses to furnish Medicare-covered DMEPOS.

DMEPOS suppliers have long presented to the Medicare program an elevated risk of fraud, waste, and abuse. In recognizing this threat, CMS over the years has established particularly stringent requirements that DMEPOS suppliers must meet to enroll and maintain enrollment in Medicare. For example, DMEPOS suppliers under 42 CFR 424.518(c) are one of only six provider and supplier types that are subject to the highest and strictest level of screening during the enrollment process. (They were also one of only two types (the other being HHAs) that were originally assigned to the “high-risk” screening category when § 424.518(c) was promulgated in 2011.) This screening includes: (1) a site visit; and (2) submission of fingerprints of the supplier’s 5 percent or greater owners for a Federal Bureau of Investigation

(FBI) criminal background check. There also are other regulatory provisions besides the basic provider enrollment requirements in subpart P of 42 CFR part 424 (§§ 424.500 through 424.575) that DMEPOS suppliers must meet. With certain exceptions based on the type of DMEPOS supplier involved, these requirements include, but are not limited, to the following:

- Compliance with the DMEPOS supplier standards outlined in § 424.57(c).
 - Acquisition and maintenance of a surety bond consistent with § 424.57(d).
 - Compliance with DMEPOS quality standards.
 - Accreditation by a CMS-approved DMEPOS accrediting organization.
- Such has been our longstanding concerns about DMEPOS program integrity that DMEPOS suppliers are also one of two only Medicare provider or supplier types (the other being Medicare Diabetes Prevention Programs) with an enrollment application (Form CMS–855S) devoted exclusively to a single provider/supplier type.

(B) Continued Program Integrity Concerns With DMEPOS Suppliers

Despite these and other DMEPOS program integrity efforts we have undertaken, serious concerns remain. Indeed, numerous Office of Inspector General (OIG) reports since 1998 have noted such payment safeguard issues associated with DMEPOS suppliers. Two recent OIG reports are illustrative.

In May 2024, the OIG issued a report titled “Medicare Remains Vulnerable to Fraud, Waste, and Abuse Related to Off-the-Shelf Orthotic Braces, Which May Result in Improper Payments and Impact the Health of Enrollees” (A–09–21–03019). The report noted that prior OIG reviews identified vulnerabilities associated with orthotic braces, such as: (1) questionable DMEPOS supplier billing practices; (2) improper payments made for braces that were not medically necessary or were not documented; and (3) fraud related to off-the shelf (OTS) braces.³⁸ The May 2024 report also cited issues related to Medicare’s oversight of OTS braces, including the following:

- Medicare paid for OTS braces that were—
 - ++ Ordered by suppliers that did not have treating relationships with beneficiaries.
 - ++ Marketed to beneficiaries by telemarketers using prohibited direct solicitation.

³⁸ <https://oig.hhs.gov/reports/all/2024/medicare-remains-vulnerable-to-fraud-waste-and-abuse-related-to-off-the-shelf-orthotic-braces-which-may-result-in-improper-payments-and-impact-the-health-of-enrollees/#:-:>

- Payments to suppliers for fraudulently billed OTS braces have cost Medicare millions of dollars.³⁹

Given these issues, the OIG recommended that, among other things, CMS analyze DMEPOS supplier billing patterns, identify emerging fraud schemes related to OTS braces, and use CMS’s authority to prevent further losses to the Medicare program.⁴⁰

Another OIG report titled “Medicare Improperly Paid Suppliers for Intermittent Urinary Catheters” (A–09–22–03019) was released in February 2025. Citing the ongoing risk of improper payments, the OIG performed a nationwide audit to determine whether Medicare paid suppliers for catheters consistent with Medicare requirements for catheters furnished to beneficiaries between July 2021 through June 2022.⁴¹ The OIG found that payments for 15 sample items did not comply with Medicare requirements, in some cases because suppliers were non-compliant with requirements for catheter refills, proof of delivery, or a standard written order.⁴² This resulted in approximately \$35.1 million in improper payments.⁴³ Even before this report, however, CMS in early 2023 had identified a concerning rise in urinary catheter billings attributed to a fraud scheme involving 15 DMEPOS companies that had recently changed ownership. CMS’ own investigation of this matter determined that: (1) Medicare beneficiaries did not receive catheters from these DMEPOS companies and were not billed directly; (2) physicians did not order these supplies; and (3) the supplies were not needed.⁴⁴ Although CMS took prompt action to address this matter, including stopping payments from being made to these suppliers and revoking the Medicare enrollments of all 15 suppliers, both the OIG report and our investigation underscored the program integrity issues in the DMEPOS arena.⁴⁵

Yet these issues go far beyond the aforementioned OIG and CMS reviews. There have been a considerable number of criminal convictions and other findings over the years involving DMEPOS suppliers. Below is a non-exhaustive list of several recent cases:

³⁹ *Ibid.* pp. 7–12.

⁴⁰ *Ibid.*, p. 13.

⁴¹ <https://oig.hhs.gov/reports/all/2025/medicare-improperly-paid-suppliers-for-intermittent-urinary-catheters/>.

⁴² *Ibid.*

⁴³ *Ibid.*

⁴⁴ <https://www.cms.gov/files/document/cpi-urinary-catheter-case-study.pdf>. See also <https://oig.hhs.gov/fraud/consumer-alerts/consumer-alert-catheter-scam/>.

⁴⁵ *Ibid.*

- In May 2024, a Florida man was sentenced to 96 months in prison for his role in a DMEPOS kickback scheme. He and others owned and operated marketing call centers and telemedicine companies through which they secured physicians' orders for DMEPOS for Medicare beneficiaries without regard to medical necessity. They then furnished the physicians' orders in exchange for bribes from DMEPOS companies that provided the braces to beneficiaries, causing over \$11 million in losses to the Medicare program.⁴⁶

- A California woman was sentenced in December 2023 to 15 years in prison for billing Medicare for over \$24 million by submitting fraudulent claims for medically unnecessary DME—mostly power wheelchairs (PWC)—and PWC repairs. As the *de facto* owner of two DMEPOS supplier companies (both of which were Medicare-enrolled in the names of her out-of-state relatives), the individual orchestrated a scheme in which she paid marketers for patient referrals and then directed them to take patients to physicians, who prescribed medically unnecessary DME (including PWCs) that her companies used to submit fraudulent claims to Medicare. Two other defendants were convicted in this case, including one who worked at both DMEPOS companies as a repair technician.⁴⁷

- A Texas man in March 2023 was sentenced to 66 months in prison for conspiring to defraud Medicare of more than \$2 million. The individual, who owned and operated a Virginia DMEPOS supplier, submitted thousands of fraudulent claims for DME, such as back and knee braces. Working with other companies and individuals, the DMEPOS supplier would unlawfully obtain the personal identification information of Medicare beneficiaries, mail them braces that they never wanted or needed, and then submit fraudulent claims to Medicare.⁴⁸

- In September 2023, a federal district court entered a judgment against a Virginia DMEPOS supplier for damages and penalties under the False Claims Act for over \$12 million. In its complaint filed in district court, the United States alleged that over a nearly 6-year period, Medicare paid the supplier over \$600,000 for medical braces furnished to Medicare beneficiaries related to DMEPOS

prescriptions that the supplier illegally purchased from marketing companies. The DMEPOS supplier paid a fee for each prescription that it purchased and then used these prescriptions (along with personal and medical data provided by the marketing companies) to submit 923 fraudulent Medicare claims.⁴⁹

- A California father and son in March 2024 were sentenced to prison for their roles in fraudulently receiving over \$21 million in Medicare payments. The pair, along with others, conspired to commit Medicare fraud by billing for medically unnecessary DME, such as knee, ankle, shoulder, wrist and back braces. They had established two DMEPOS supplier companies; to find customers, they entered into sham agreements with “marketing” companies that, instead of marketing, provided information about Medicare beneficiaries for \$125 to \$350 each. The packets included, among other things, a signed prescription from a physician (obtained via telemedicine) claiming that the brace was medically necessary for the beneficiary. In almost all cases, however, the physician signing the prescription had no previous doctor-patient relationship with the beneficiary. The two men then billed Medicare through their DMEPOS companies for the unnecessary items.⁵⁰

- A Texas man was sentenced to prison in February 2024 for conspiring to pay health care kickback payments for unnecessary DME, resulting in over \$20 million in claims to—and \$13 million in payments from—the Medicare program. The individual owned and operated two DMEPOS suppliers. Through another entity, the individual secured access to thousands of Medicare beneficiaries' information by paying, on a weekly basis, kickbacks in exchange for signed physician orders for the braces.⁵¹

- In August 2023, a Florida man was sentenced to prison for conspiring to defraud the Medicare program. The individual and another person illegally paid kickbacks of over \$565,000 to buy fraudulent DMEPOS orders, including orders purportedly “signed” by physicians who, in fact, never signed or authorized these orders and did not know their names and identities were being used in this manner. They also

resold some of the fraudulent orders to other DMEPOS suppliers—receiving more than \$425,000 in proceeds—so that those suppliers, in turn, could fraudulently bill Medicare for the DMEPOS. Furthermore, the two individuals acquired five of their own fraudulent DMEPOS supply companies and themselves used fraudulent DMEPOS orders to file more than \$11 million in fraudulent Medicare claims.⁵²

- A Texas woman in December 2024 was sentenced to 60 months in prison for conspiracy to commit health care fraud. According to court documents, she engaged in fraudulent billing practices as the owner of a DMEPOS supplier. Her scheme involved substituting and providing lesser valued items to Medicare beneficiaries and then billing Medicare for the greater valued items. The items were primarily continence supplies and included adult diapers, wipes, and bed liners.⁵³

- Several DMEPOS suppliers in January 2024 agreed to pay \$2.1 million to resolve allegations that they violated the False Claims Act by submitting false claims for payment to Medicare and other federal health care programs. The settlement resolved resolve allegations that over a 9-year period, the companies:

- ++ Sold used beds but billed federal health care programs as if they were new beds.

- ++ Sold various hospital beds and pressure support surfaces to beneficiaries of federal health care programs under a miscellaneous code, which sometimes resulted in the federal program paying a higher price.

- ++ Presented claims to the federal government and its contractors that mischaracterized travel time as DMEPOS repair time in order for it to be reimbursable by federal health care programs.⁵⁴

- A Florida man was sentenced to 87 months in prison in September 2022 for his role in using a DMEPOS company to commit Medicare and Medicaid fraud. Having established the company, he sought to conceal his role as its true owner who exercised control over the company (and the fraud) by listing a nominee or “straw” owner as the owner on its corporate records and bank account. The individual admitted that

⁴⁶ <https://www.justice.gov/usao-nj/pr/florida-man-sentenced-96-months-prison-role-multimillion-dollar-health-care-kickback>.

⁴⁷ <https://www.justice.gov/usao-cdca/pr/redondo-beach-woman-sentenced-15-years-prison-leading-24-million-scam-billed-medicare>.

⁴⁸ <https://www.justice.gov/usao-edva/pr/texas-man-sentenced-2-million-medicare-fraud>.

⁴⁹ <https://www.justice.gov/usao-edva/pr/virginia-medical-equipment-provider-ordered-pay-12-m-medicare-fraud-scheme-civil>.

⁵⁰ <https://www.justice.gov/usao-sdca/pr/father-and-son-duo-sentenced-prison-21-million-dollar-medicare-scheme>.

⁵¹ <https://www.justice.gov/usao-ndga/pr/operator-durable-medical-equipment-companies-sentenced-healthcare-kickback-scheme>.

⁵² <https://www.justice.gov/usao-sdny/pr/florida-business-owner-sentenced-five-years-prison-defrauding-medicare-more-11-million>.

⁵³ <https://www.justice.gov/usao-wdtx/pr/el-paso-medical-equipment-supplier-sentenced-federal-prison-17-million-healthcare>.

⁵⁴ <https://www.justice.gov/usao-sc/pr/durable-medical-equipment-companies-pay-millions-false-claims-settlement>.

he—and not a straw owner—bought lists of Medicare “patients” and then directed a “biller” to submit fraudulent claims to Medicare for DMEPOS that a physician did not prescribe, that were not medically necessary, and that were not being supplied to any Medicare beneficiary or Medicaid recipient. During a three-month period—and under the individual’s direction—the supplier submitted over \$2.3 million in fraudulent claims to Medicare and Medicaid and was paid over \$1.6 million. The proceeds of the fraud were transferred from the supplier’s account to accounts held in the names of shell companies. Those proceeds were then withdrawn from the shell company accounts by others so they could not be traced to the individual.⁵⁵

- A Florida man was sentenced to prison in October 2022 for submitting fraudulent claims to Medicare. The individual owned a DMEPOS supplier. The supplier purported to provide DMEPOS to eligible Medicare beneficiaries. Over a five-month period, the supplier submitted approximately \$2.2 million in fraudulent Medicare claims (and received \$1.4 million in Medicare payments) for DMEPOS that the business never provided and that Medicare beneficiaries never requested.⁵⁶

- A Texas couple pled guilty in April 2025 to defrauding Medicare. The couple operated a DMEPOS supplier that claimed to provide parts and repairs for power wheelchairs, among other services. They admitted that they received millions of dollars for parts and repairs that were never performed or provided. Medicare was billed approximately \$14 million for power wheelchairs, parts and repairs for just 37 Medicare beneficiaries between 2019 and 2023 as a result of their scheme.⁵⁷

- A Georgia woman pled guilty in June 2024 to an information charging her with conspiracy to commit health care fraud. The individual and her conspirators owned, operated, and had a financial interest in DMEPOS companies through which they obtained physicians’ orders for DMEPOS for Medicare beneficiaries without regard to medical necessity. They obtained the DMEPOS orders using marketing call centers and telemedicine companies, caused the submission of false and

fraudulent Medicare claims, and paid illegal kickbacks.⁵⁸

- A South Carolina man was sentenced to 9 years in prison in March 2024 for his role in a nearly \$100 million healthcare fraud scheme. The individual controlled and operated at least 10 DMEPOS companies located throughout the United States. The person and his conspirators used these companies to submit false and fraudulent claims to Medicare for braces that were not medically necessary and/or were obtained through the payment of kickbacks and bribes. Specifically, the companies entered into agreements with an offshore, advertised call center to purchase physicians’ orders so the DMEPOS companies could bill Medicare. When a Medicare beneficiary called the applicable 1–800 number, the beneficiary would be screened for eligibility and then convinced that the beneficiary needed a brace and oftentimes upsold on other braces. The call center would then contact a telemedicine company whose physician or nurse practitioner would issue a prescription without regard to the medical necessity. Beneficiaries were prescribed braces without ever being examined by, seeing, or, in some instances, even speaking to a medical professional.⁵⁹

- A North Carolina woman in April 2023 pled guilty to an information charging her with one count of conspiracy to commit health care fraud. The individual owned and operated various DMEPOS suppliers through which she obtained physicians’ orders for DMEPOS. She paid an individual and others for each DMEPOS order for braces provided to her DMEPOS supply companies. She then billed Medicare for the DMEPOS orders that she obtained in exchange for kickbacks. She observed indicators that these DMEPOS orders were not medically necessary, in part because Medicare beneficiaries would frequently call to complain that they had not ordered the DMEPOS that they received. In addition, to disguise the scheme she put her DMEPOS supplier companies in the names of nominee owners, including her sisters and a friend.⁶⁰

- A Kentucky DMEPOS supplier agreed to pay \$200,000 to resolve allegations that it violated the False

Claims Act by fraudulently billing Medicare and Medicaid for respiratory devices (specifically, non-invasive ventilators) that beneficiaries did not need or use.⁶¹

Elderly diabetics have also been a target for DMEPOS suppliers. For example, a Florida diabetic shoe company and its president agreed in January 2022 to pay over \$5.5 million to settle claims brought under the False Claims Act that it sold custom diabetic shoe inserts that were not actually custom-fabricated in accordance with Medicare standards. The company billed Medicare for the custom version or sold the inserts to other providers who then billed Medicare, which allowed the company to produce and sell more inserts and increase profits by “cutting corners.”⁶²

All of the foregoing indicates several things. First, DMEPOS fraud, waste, and abuse is still a very significant problem, putting hundreds of millions (even billions) of taxpayer dollars at risk and potentially resulting in patient harm, such as in cases where beneficiaries use unnecessary or substandard items. The OIG reiterated the problem in 2024 when it stated: “Although CMS has a number of safeguards in place to prevent bad actors from billing DMEPOS in Medicare, fraudulent billing for DMEPOS continues to be a major concern. Recent cases demonstrate that DMEPOS continues to be a target of fraudulent billing and that new schemes have developed.”⁶³ Second, DMEPOS fraud schemes do not necessarily follow a consistent pattern but can vary widely in their particular facts. Third, DMEPOS fraud, waste, and abuse is not restricted to certain types of items or certain areas of the country but occurs with numerous different product types and in many geographic areas. Considering the wide and ever-changing range of payment safeguard risks associated with DMEPOS supplies, we must continually take measures to address them.

(2) Quality Standards

Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added section 1834(a)(20) of the Act. Section 1834(a)(20) of the Act requires the Secretary to establish and implement DMEPOS quality standards for suppliers

⁵⁵ <https://www.justice.gov/usao-sdfl/pr/miami-man-who-used-durable-medical-equipment-company-front-health-care-fraud-sentenced>.

⁵⁶ <https://www.justice.gov/usao-sdfl/pr/durable-medical-equipment-company-owner-sentenced-health-care-fraud>.

⁵⁷ <https://www.justice.gov/usao-sdtx/pr/harlingen-couple-guilty-multimillion-dollar-medicare-fraud-scheme>.

⁵⁸ <https://www.justice.gov/usao-nj/pr/georgia-chiropractor-admits-149-million-health-care-fraud-and-kickback-scheme-related>.

⁵⁹ <https://www.justice.gov/usao-sc/pr/mt-pleasant-man-sentenced-nine-years-federal-prison-role-one-largest-medicare-fraud>.

⁶⁰ <https://www.justice.gov/usao-nj/pr/north-carolina-woman-admits-participating-health-care-fraud-scheme>.

⁶¹ <https://www.justice.gov/usao-edky/pr/floyd-county-company-agrees-pay-200000-resolve-allegations-fraudulent-billing>.

⁶² <https://www.justice.gov/usao-sdfl/pr/diabetic-shoe-company-agrees-pay-55-million-resolve-false-claims-act-allegations>.

⁶³ <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000867.asp>.

of certain items. As stated in section 1834(a)(20)(D) of the Act, these items are as follows:

- Covered items, as defined in section 1834(a)(13) of the Act, for which payment may be made under section 1834(a) of the Act;
- Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4) of the Act; and
- Items described in section 1842(s)(2) of the Act (for example, medical supplies; home dialysis supplies and equipment; therapeutic shoes; parenteral and enteral nutrients, equipment, and supplies).

Section 1834(a)(20)(E) of the Act authorizes the Secretary to establish the DMEPOS quality standards by program instruction or otherwise after consultation with representatives of relevant parties. CMS first established quality standards via sub-regulatory guidance in 2006 and has updated them as needed since then. Currently accessible at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html>, these standards address matters such as the following:

- Administration
- Financial, human resources, and information management
- Equipment and item delivery and set-up
- Patient and caregiver training and instruction
- Patient follow-up.

The standards are both extensive and detailed because we must confirm that the supplier is bona fide and legitimate. Per § 424.57(c)(24), all DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards to enroll in and bill Medicare.

(3) Accreditation

Consistent with section 1834(a)(20)(F)(i) of the Act (and with certain exceptions), DMEPOS suppliers must be accredited by a CMS-approved accrediting organization (AO) to enroll in and bill Medicare. The main purpose of accreditation is to confirm that the supplier meets the DMEPOS quality standards. The accreditation process has been in effect since 2006.

Although § 424.57(c)(24) states that all DMEPOS supplier locations (owned or subcontracted) must be separately accredited, section 1834(a)(20)(F) of the Act exempts certain individuals from the accreditation requirements unless the Secretary determines the quality standards specifically apply to them. The following DMEPOS supplier types are currently exempted:

- Physicians
- Other eligible professionals (as defined in section 1848(k)(8) of the Act), such as a physician assistant or nurse practitioner
- Opticians
- Prosthetists and orthotists
- Qualified audiologists

Certain types of DMEPOS items are also exempt from accreditation, including: (1) DME drugs (inhalation drugs and DME pump-infused drugs); (2) HHAs' medical supplies; and (3) other Part B drugs, such as immunosuppressive and antiemetic drugs.

Per section 1834(a)(20)(B) of the Act, the Secretary designates and approves DMEPOS AOs, of which there presently are eight. To become an AO or be retained or reapproved as one, the AO must meet the requirements of § 424.58. As addressed in greater detail throughout section VI.B. of this proposed rule, these requirements include, but are not limited to the following:

- Completing the application process, which includes the submission of detailed information about the AO's operations and procedures.
- Undergoing various CMS reviews.
- Furnishing ongoing data to CMS about its activities, such as its accreditation decisions, complaints received about suppliers, etc.

In general, DMEPOS suppliers may choose the AO it wishes to accredit them. In performing its DMEPOS accreditation activities—and subject to CMS approval—an AO generally has some discretion in the operational aspects of its review of a supplier's request for accreditation. However, one critical and common component of the review process is the AO's performance of an on-site survey of the supplier. Along with the AO's review of the information the supplier furnishes as part of its accreditation application, the survey enables the AO to examine first-hand the supplier's operations and credentials to help ascertain compliance with the quality standards. Per our subregulatory guidance, DMEPOS suppliers currently must be surveyed once every 3 years following initial accreditation.

(4) Concerns About the Existing DMEPOS Accreditation Process

We are proposing various regulatory changes to our current DMEPOS accreditation process to improve and strengthen it. There are several reasons for this.

First, we have seen an increased number of reports of accredited suppliers not meeting the quality

standards, which has raised questions as to the efficacy of some AO accreditation surveys and reviews. Second, given the aforementioned AO discretion in various aspects of its DMEPOS accreditation processes, we are concerned that differences between the AOs in this regard could lead to inconsistencies in how quality standard compliance determinations are made. Third, although surveys are typically part of the DMEPOS accreditation process, not every supplier receives one. This is especially true for large chain suppliers with 25 or more separately enrolled locations (such as chain pharmacies). We believe this is a potential vulnerability in our enforcement of the DMEPOS accreditation requirement. Fourth, while § 424.58 outlines certain components of the DMEPOS accreditation process (for example, AO data submission to CMS, applying to become an AO), it does not address other important topics that, in our view, should be outlined in regulation. Indeed, CMS regulations regarding the accreditation of certified providers, certified suppliers, and home infusion therapy (HIT) suppliers (found in 42 CFR part 488) contain more extensive provisions than does § 424.58, and we believe some of the protections they afford the Medicare program in facilitating provider and supplier compliance should be duplicated in § 424.58. Fifth, we have since 2006 neither reapproved any AOs nor undertaken a full reassessment of the performance and suitability of our existing AOs. We believe both are now necessary—particularly considering this long passage of time—so we can ensure the DMEPOS accreditation program is functioning effectively. Sixth, and perhaps most importantly, the unique, aforementioned program integrity risks that DMEPOS suppliers continue to pose require, in our view, stricter oversight of the process that helps determines their qualifications.

An additional criminal case underscores our concerns. In March 2025 an individual pled guilty in Federal court (Southern District of Florida) to accepting cash bribes and self-dealing as part of a conspiracy to impede and obstruct the lawful functions of the U.S. Department of Health and Human Services (HHS) and CMS in their administration and oversight of the Medicare program.⁶⁴ According to court documents, the person was a contractor for a DMEPOS

⁶⁴ <https://www.justice.gov/usao-sdfl/pr/miami-inspector-pleads-guilty-scheme-obstruct-us-department-health-and-human-services>.

AO and performed inspections of hundreds of DMEPOS suppliers for compliance with the quality standards. The individual—

- Accepted cash bribes from numerous owners of DMEPOS suppliers to facilitate and expedite the accreditation process so these companies could enroll in and bill Medicare;
- Along with the individual's immediate family, formed DMEPOS companies in the names of family members to conceal the individual's own personal interest in the companies. The person then sold some of these companies to others, having increased their value as Medicare-enrolled DMEPOS suppliers; and
- Directly or indirectly owned some of the suppliers the individual surveyed.⁶⁵

Considering that this case, and perhaps other situations where unqualified suppliers were accredited, may have resulted in many millions of dollars in improper Medicare payments, we believe we must exercise much closer scrutiny over DMEPOS supplier accreditation in general and DMEPOS AOs in particular to prevent such instances from occurring.

In addition, certain CMS concerns about provider and supplier accreditation are not limited to DMEPOS suppliers. In the February 15, 2024, **Federal Register** (89 FR 11996), we published a proposed rule titled “Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions”. This proposed rule would update and supplement provisions in 42 CFR part 488 (hereafter simply part 488) to enhance CMS' oversight of certified provider and supplier AOs; examples of proposed enhancements included addressing conflicts of interest and establishing additional regulatory definitions and procedures for clarity and consistency. We seek to do likewise for DMEPOS accreditation in the subject proposed rule in part by incorporating several provisions in the February 15, 2024, proposed rule into § 424.58, though with modifications to accommodate the unique characteristics of DMEPOS accreditation.

(5) Linkage and Conclusion

We previously noted our desire and obligation to continually strive to reduce DMEPOS fraud, waste, and abuse and, in turn, to limit improper payments and help protect beneficiaries. Although means such as high-risk

screening, site visits, surety bonds, and our existing accreditation program have assisted in this regard, the criminal cases and other concerning situations we have seen make clear that more is needed. Our current DMEPOS payment safeguards are not enough. We view stricter accreditation requirements for both the AOs and DMEPOS suppliers as a mechanism that could effectively supplement our existing measures and halt a certain degree of ongoing fraud, waste, and abuse by facilitating closer and more frequent oversight of the suppliers. While the remainder of this section (section VI.B. of this proposed rule) describes our specific proposals in detail, we present several scenarios—similar to some of the aforementioned criminal cases—where a strengthened accreditation program could help limit or prevent the activities in question:

- Scenario 1—Supplier U is accredited by a DMEPOS AO and is Medicare-enrolled. It undergoes a stock transfer of 60 percent 15 months after initially enrolling, and the new owner assumes control of the business. The new owner is uncommitted to complying with the quality standards and the quality of U's services consequently deteriorate, potentially harming beneficiaries for a considerable period because U's 3-year deadline for another survey will not arrive for another 21 months. However, with more frequent surveys and reaccreditations, such as when the ownership change occurred, the AO could more quickly and closely scrutinize the supplier under its new ownership—before beneficiaries are harmed and further payments to the non-compliant supplier are made.

- Scenario 2—Supplier V is accredited and Medicare-enrolled. Encountering financial problems 1 year into its accreditation, V begins purchasing very substandard (and thus less expensive) DMEPOS in order to cut costs. Without another survey and reaccreditation of V for 2 more years, CMS might have no means of knowing that V's poor-quality products are being furnished to beneficiaries, that these individuals are possibly being harmed, and that Medicare could be paying tens of thousands of dollars for items that do not meet Medicare requirements.

- Scenario 3—Supplier W is accredited and Medicare-enrolled. Nine months after accreditation—or 27 months before its next survey—it begins to engage in fraudulent practices, a few of which are similar to those addressed in the previously noted criminal cases. To help shield its activities, W does not keep records that comply with the DMEPOS quality standards pertaining to

financial management, such as: (1) implementing financial management practices that ensure accurate accounting and billing; and (2) maintaining accounts that link equipment and item(s) to the beneficiary. If surveys and accreditations were required to be annual, however, W's activities could be detected earlier and, given W's failure to comply with the above financial management quality standards, its accreditation and enrollment could be revoked and many Medicare dollars saved.

- Scenario 4—Accredited and enrolled Supplier X becomes so deficient over a multi-month timeframe in (1) furnishing instructions to beneficiaries on how to use equipment and (2) properly setting up the equipment, that several beneficiaries are injured towards the end of this period. X also repeatedly failed to conduct investigations of beneficiary complaints about X's actions. If surveys could be performed with greater regularity, though, the AO could have discovered these violations of various quality standards involving product safety and consumer services before any harm occurred.

- Scenario 5—Y has been a DMEPOS AO for 1 year. It hires two individuals as managing employees who will also participate in surveys and accreditation decisions. One is a physician whose medical license is currently revoked for engaging in fraudulent activity, while the other is a non-physician practitioner whose Medicare enrollment is revoked for furnishing false or misleading information on the Medicare enrollment application. This could raise concerns about the integrity of Y's operations—particularly the physician's participation in surveys—yet existing § 424.58 contains no prohibitions against such hirings.

- Scenario 6—Entity Z seeks to become a DMEPOS AO. As part of its application, it submits the data currently required in § 424.58(b). This data, though, does not include information about the AO's policies and procedures for avoiding conflicts of interest and the appearance thereof involving individuals who perform surveys for the AO. In fact, there is no explicit prohibition in § 424.58 against, for example, an AO surveyor making an accreditation decision regarding a DMEPOS supplier in which the surveyor has an ownership interest. Given this, AO Z has three individuals who perform surveys of suppliers that the individuals partially own. These suppliers did not meet the quality standards, but the surveyors found them

⁶⁵ Ibid.

compliant regardless, meaning the suppliers would improperly receive Medicare payments despite their quality standard non-adherence. Yet if CMS had had application information on Z's conflict of interest policies and § 424.58 contained a prohibition against such activities, the obvious conflict of interest involving Z could possibly have been avoided and Medicare dollars preserved.

b. Legal Authorities

There are several principal categories of legal authorities for our proposed provisions:

- Section 1834(a)(20)(A) of the Act requires the Secretary to establish and implement quality standards for the suppliers of the items and services described in section 1834(a)(20)(D) of the Act to be applied by recognized independent accrediting organizations.
- Notwithstanding section 1865(a) of the Act, section 1834(a)(20)(B) of the Act requires the Secretary to designate and approve one or more independent AOs for purposes of applying the quality standards referenced in section 1834(a)(20)(A) of the Act.
- Section 1834(a)(20)(F)(i) of the Act (and with certain exceptions) requires the Secretary to mandate that suppliers of the items and services described in section 1834(a)(20)(D) of the Act submit to the Secretary evidence of accreditation by an AO designated under section 1834(a)(20)(B) of the Act.
- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

2. DMEPOS Accreditation Proposed Provisions

Section 424.58, which governs DMEPOS accreditation, contains the following principal paragraphs:

- Paragraph (a)—Purpose of § 424.58
- Paragraph (b)—AO application and reapproval application procedures
- Paragraph (c)—Ongoing responsibilities of AOs
- Paragraph (d)—Continuing Federal oversight of approved AOs
- Paragraph (e)—AO reconsiderations/appeal rights

Considering the extent of our proposed changes to § 424.58, we propose to entirely reorganize the current paragraph structure and designations. Existing provisions would be moved, revised, deleted, or supplemented as warranted. We believe this restructuring would help stakeholders better understand requirements of § 424.58. Except for

current paragraph (a) or as otherwise noted, all paragraph designations are labeled as proposed new provisions even though the provision may already exist in current § 424.58 under a different paragraph. (For example, current paragraph (b) would be noted as new paragraph (c) even though § 424.58 presently has a paragraph (c)). To the extent needed, we will in this proposed rule cross-reference current § 424.58 paragraph designations to new ones to further assist stakeholders.

In this proposed rule, and unless otherwise indicated—

- “Supplier” refers to a DMEPOS supplier, including its individually enrolled location;
- “AO” refers to an accrediting organization with a DMEPOS accreditation program;
- “Accreditation program” or “program” refers to a DMEPOS accreditation program; and
- “Quality standards” refers to DMEPOS quality standards.

a. Definitions (New § 424.58(b))

We propose several new definitions in § 424.58(b). We believe they would help clarify the regulatory provisions to which they relate.

First, we propose to define “complaint” as an allegation from any party (and via any format) that one of the AO's accredited suppliers may be non-compliant with one or more quality standards or other applicable CMS requirement; the complaint need not involve actual or potential beneficiary harm. As part of the AO approval or reapproval process, current § 424.58(b)(1)(ix) requires the AO to establish procedures for responding to and investigating complaints against its accredited suppliers. Existing § 424.58(c)(1)(iii), meanwhile, requires the AO to monthly provide CMS with notice of such complaints. Given these requirements, we believe a clear definition of “complaint” is warranted. Moreover, we do not believe beneficiary harm should be a prerequisite for meeting the complaint definition, for any type of non-compliance with the quality standards or other applicable CMS requirement is of concern to us.

Second, we propose to define “immediate jeopardy” as a situation where the supplier's non-compliance with one or more quality standards or other applicable CMS requirement has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient or to the health and safety of the general public. This definition—with minor modifications for purposes of DMEPOS accreditation—has precedent in that it mirrors the term's definition in

§ 488.1 regarding certified providers and certified suppliers. The definition is needed for § 424.58 partly because AOs, under current paragraph (c)(4) thereof, must notify CMS within 2 calendar days of a supplier's deficiency that poses immediate jeopardy.

Third, we propose to define “reasonable assurance” as meaning that an AO has demonstrated to CMS' satisfaction that—

- Its accreditation program requirements meet or exceed the Medicare program requirements;
- The suppliers the AO accredits meet or exceed Medicare requirements; and
- The AO is compliant with all provisions of § 424.58.

As discussed further in this section VI.B. of this proposed rule, we believe AOs should demonstrate that their accreditation programs comply with § 424.58 and all other CMS requirements, hence the need for a reasonable assurance definition. We note that paragraph (1) of our proposed definition duplicates that in § 488.1 in both terminology and purpose.

Fourth, we propose to define “unannounced survey” as meaning:

- A survey conducted without any prior notice of any type (through any means of communication or forum) to the supplier to be surveyed, such that the supplier does not expect the survey until the surveyors arrive; and
- The AO schedules its surveys so that suppliers cannot predict when they will be performed.

It is critical that DMEPOS supplier surveys be unannounced, as they currently are, so that a non-compliant supplier cannot use prior notice of a survey to remedy its deficiencies solely to pass the survey, after which it may resume its non-adherence. Given this, we believe our proposed definition of this term—which, with technical modifications, is similar to the proposed definition of this term in the previously noted February 15, 2024, proposed rule—will emphasize to AOs that no early notification of any kind is permitted.

We solicit comment on the propriety of these definitions and welcome any suggested edits thereto.

b. Initial Application for Approval of AO's Accreditation Program (New § 424.58(c))

Existing § 424.58(b) outlines the process by which an entity may apply or reapply to become an AO. While the processes for both are largely similar, we propose to separate them into two paragraphs for ease of comprehension. Initial application procedures would be

addressed in new paragraph (c) and reapproval application procedures in new paragraph (d).

Current § 424.58(b)(1) outlines information that AOs must submit as part of the application process. This data is intended to help CMS understand the AO's background, operations, planned procedures, skill, number of staff, etc. However, we have not revisited these data elements via rulemaking since promulgation in 2006. Considering, too, the previously noted lack of CMS reapproval or full reassessment of AOs for many years, we believe that more detailed and comprehensive data should be submitted so we can fully ascertain a current or prospective AO's qualifications. We accordingly propose the following changes and additions to existing § 424.58(b)(1), which would be redesignated as new paragraph (c)(1).

(1) Reasonable Assurance Opening Statement (New § 424.58(c)(1))

The opening part of existing paragraph (b)(1) states that an AO applying for approval or reapproval of its DMEPOS accreditation program must furnish certain information to CMS. This requirement would serve as the opening statement for new § 424.58(c)(1) but with two revisions to its current language. First, we would remove the reference to "re-approval" since reapproval application processes would be addressed separately in new § 424.58(d). Second, we would replace the current phrase "the following to CMS:" with "all the following information and materials to demonstrate that the accreditation organization provides reasonable assurance (as defined in paragraph (b) of this section) regarding its program." The new language, which is akin to that in the opening paragraph of § 488.5(a), would emphasize that it would not be enough to merely submit the required information. Rather, the data must be sufficient to give CMS reasonable assurance.

(2) Confirmation of Compliance (New § 424.58(c)(1)(iii))

Existing § 424.58(b)(1)(iii), which would become new § 424.58(c)(1)(iii), starts with language that details the AO's description of its operational processes. We propose to revise this to require a detailed description of the organization's operational, survey, and other accreditation processes to confirm that the suppliers it accredits meet or exceed the DMEPOS quality standards and Medicare program requirements. We believe this expanded data would give us a broader understanding of the

AO's procedures in full, instead of those simply relating to operations.

We propose two other changes involving this paragraph. Current paragraph (b)(1)(iii) contains six elements of the required description, such as: (1) an explanation of the frequency with which surveys will be performed; and (2) guidelines and instructions to surveyors. To improve organizational clarity, we propose to designate these elements as new § 424.58(c)(1)(iii)(A) through (F) in the same respective order they are listed in existing (b)(1)(iii). In addition, new paragraph (c)(1)(iii)(G) would require the description to address how the AO determines whether to perform a survey in situations where it has the discretion to do so; this would have to include a suggested methodology for sampling locations for surveys under a single tax identification number or organization. As explained further in section VI.B.2. of this proposed rule, surveys of DMEPOS suppliers may not be required in all instances. That is, CMS may permit the AO to determine whether a survey is necessary; this could involve, for example, sampling, whereby the AO uses a formula to determine which locations within a particular group (such as a large chain pharmacy) should be surveyed. To help us understand the factors and criteria the organization will consider in its determination and, more importantly, whether it will exercise its discretion prudently, we believe new § 424.58(c)(1)(iii)(G) is necessary.

(3) Redesignation of Existing Data Submission Provisions (New § 424.58(c)(1)(i), (ii), (iv), (v), (vi), and (vii)(A), (B), and (C))

Current §§ 424.58(b)(1)(i), (ii), and (iv) through (vii)(A) through (C) describe additional information the AO must furnish. Although we are not proposing to change the content of these paragraphs, they would constitute, respectively, new §§ 424.58(c)(1)(i), (ii), and (iv) through (vii)(A) through (C).

(4) Conflicts of Interest, Consulting Services, and Number of Surveyors (New § 424.58(c)(1)(vii)(D) and (E))

We propose additional requirements in new § 424.58(c)(1)(vii).

Paragraph (D) would require the AO to explain in detail its policies and procedures for avoiding conflicts of interest and the appearance thereof involving individuals who conduct surveys or participate in accreditation decisions. This must include the organization's policies and procedures for all of the following:

- The separation of its consulting services from its accreditation services.

- Protecting the integrity of the DMEPOS AO's accreditation program (including the requirements of proposed § 424.58(m) and (n) (discussed later in this section VI.B. of this proposed rule).

- The prevention and handling of potential or actual conflicts of interest that could arise from situations in which a DMEPOS AO owner, surveyor, or employee has an interest in, or relationship with, a DMEPOS supplier to which the AO provides accreditation services. Such interests or relationships include, but are not limited to, the following:

- ++ Being employed as a DMEPOS AO surveyor.

- ++ Being employed by a DMEPOS supplier that is accredited by the DMEPOS AO.

- ++ Having an ownership, financial, or investment interest in a DMEPOS supplier that is accredited by the DMEPOS AO.

- ++ Serving as a director of or trustee for a DMEPOS supplier that is accredited by the DMEPOS AO.

- ++ Serving on a utilization review committee of a DMEPOS supplier that is accredited by the DMEPOS AO.

- ++ Accepting fees or payments from a DMEPOS supplier or group of DMEPOS suppliers that is/are accredited by the DMEPOS AO.

- ++ Accepting fees for personal services, contract services, referral services, or for furnishing supplies to a DMEPOS supplier that is accredited by the DMEPOS AO.

- ++ Providing consulting services to a DMEPOS supplier that the DMEPOS AO accredits.

- ++ Having members of their immediate family engaged in any of the above stated activities. The term "immediate family member" would be defined in proposed 424.58(b) as any person with whom the AO owner(s), surveyors or employees have a lineal or immediate familial or marital relationship, including a husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. (This definition would be included in proposed revised paragraph (b) of this section.)

- ++ Engaging in any activities during the course of the survey of the DMEPOS supplier that would be or cause a conflict of interest.

- For notifying CMS when a conflict of interest is discovered.

We would also clarify in new paragraph § 424.58(c)(1)(vii)(D)(5) that

for purposes of said paragraph, a conflict of interest exists when a DMEPOS AO, the DMEPOS AO's successors, transferees, or assigns, the DMEPOS AO owner(s), surveyors, or employees, or the immediate family members of the DMEPOS AO owners(s), surveyors and employees have an employment, business, financial or other type of interest in or relationship with a DMEPOS supplier that the DMEPOS AO accredits.

We discuss in more detail later in this proposed rule our concerns about potential conflicts of interest within a DMEPOS AO's accreditation programs. Along with the aforementioned March 2025 criminal case in the Southern District of Florida, there might be other situations where, for instance, an AO employee or owner has a familial or other relationship with a supplier the AO is about to survey. This could raise questions as to whether the AO will be entirely objective in its survey or review of the supplier at issue. We also note that the previously mentioned February 15, 2024, proposed rule would require the submission of this proposed data as part of the initial application process for AOs seeking to accredit certified providers and certified suppliers. We believe this requirement should be duplicated for DMEPOS AOs in paragraph (D). It is imperative, in our view, that DMEPOS AOs take measures to avoid such conflicts to help ensure the integrity and impartiality of its surveys and accreditation decisions; without this, unqualified suppliers could become accredited and enrolled due to subjective AO determinations, placing the Trust Funds and beneficiaries at risk.

In proposed § 424.58(c)(1)(vii)(E), we would require the AO to outline its policies and procedures for ensuring it always has an adequate number of surveyors. Our concern is that surveys could be delayed—and perhaps more importantly, a particular survey might not be performed as diligently and thoroughly—due to an insufficient number of surveyors. We therefore believe paragraph (E), which would be somewhat similar to current § 488.5(a)(6), is necessary.

(5) AO Program Deficiencies (New § 424.58(c)(1)(viii))

We propose in new § 424.58(c)(1)(viii) that the AO describe its processes for identifying and correcting deficiencies within its accreditation program. It is important for AOs to very frequently review their accreditation programs for vulnerabilities and weaknesses. Without this, AOs may perform their functions in a substandard manner. This risks the

possibility that suppliers receive inadequate scrutiny, which, in turn, could lead to them furnishing items and services while non-compliant with the quality standards. Among other things, improper Medicare payments would result. By describing its procedures for ascertaining and rectifying deficiencies, the AO can help assure CMS that its program will adhere to Medicare requirements and, if there is an indication that compliance may be at risk, it will remedy the matter.

(6) Use of Data To Ensure Program Compliance (New § 424.58(c)(1)(ix))

Existing paragraph (b)(1)(viii) requires the AO to describe its data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system. We propose to designate this paragraph as new (c)(1)(ix) and include an additional requirement (taken from § 488.5(a)(11)(i)) that the description explain how the AO uses its data to ensure that its accreditation program adheres to Medicare program requirements. Surveys and accreditation decision-making are obviously critical components of an AO's accreditation program, but there are other AO requirements under § 424.58. Since we need to ensure that the AO will adhere to all of the provisions in § 424.58, we believe an understanding of how the AO will use data to maintain this compliance is necessary.

(7) Complaint Process (New § 424.58(c)(1)(x))

Current § 424.58(b)(1)(ix) requires the AO to explain its procedures for responding to and investigating complaints against its suppliers; this includes processes for coordinating with licensing bodies, ombudsman programs, the National Supplier Clearinghouse (NSC), and CMS. A robust AO process for handling complaints is important because it involves reviewing a supplier's possible violation of a quality standard or other applicable CMS requirement. An AO's failure to properly execute this function could lead to improper Medicare payments to a non-compliant supplier.

We propose several changes to this paragraph, which would be designated as new § 424.58(c)(1)(x).

First, we would add procedures for closing out complaints as part of this information submission requirement. Responding to and investigating complaints is only part of the complaint process. We need to know how the AO would resolve a particular complaint and deem the matter concluded. That is,

we believe our analysis of the AO's qualifications regarding complaints must include an understanding of the complaint's entire life cycle from beginning to end. Without this knowledge, we cannot be assured that the AO will effectively handle the complaint to an appropriate conclusion.

Second, we would change the NSC reference to the applicable National Provider Enrollment (NPE) contractor. This is because the latter entities have replaced the NSC as CMS' DMEPOS enrollment contractors.

Third, new paragraphs § 424.58(c)(1)(x)(A) and (B), respectively, would require submission of the following information:

- The steps and research the AO will undertake in its review of the complaint; and
- How the AO determines whether, in accordance with a complaint, non-adherence to a quality standard or other applicable CMS requirement exists, including the data it considers in its review and when and how it would take action against the supplier.

As with our proposed change regarding complaint closure, we believe the data in existing § 424.58(b)(1)(ix) is insufficient to help us to determine whether the AO will handle complaints thoroughly, consistently, and diligently. Hence, we believe new § 424.58(c)(x)(A) and (B) are warranted.

(8) Redesignation of Additional Data Submission Provisions (New § 424.58(c)(1)(xi) Through (xv))

Existing § 424.58(b)(1)(x) through (xiv) address other types of information the AO must submit, such as: (1) policies and procedures for notifying CMS of non-compliant suppliers; and (2) a list of the organization's currently accredited DMEPOS suppliers. With two exceptions, we are not proposing to revise these paragraphs but only to designate them as new § 424.58(c)(1)(xi) through (xv). The two exceptions are as follows:

- In existing paragraph (xii)(B) (redesignated as new paragraph (xiii)(B)), we propose to include each supplier's accreditation product codes as data the AO must submit with its initial or reapproval application.
- In existing paragraph (xii)(C) (redesignated as new paragraph (xiii)(C)), we propose that the AO must also list each supplier's accreditation effective date with its initial or reapproval application.

Both requirements would help ensure that CMS has sufficient information on each supplier's accreditation type and status.

We note that current § 424.58(b)(1)(xv) requires the AO to agree that it will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings. We are not designating this paragraph as new § 424.58(c)(1)(xvi) because, as explained later in this proposed rule, we are proposing to include it as part of the larger agreement the AO must sign per proposed new § 424.58(c)(1)(xxiii).

(9) Knowledge and Experience (New § 424.58(c)(1)(xvi))

Section 488.1010(a)(4), which pertains to home infusion therapy supplier accreditation, requires AOs in their applications to furnish information that demonstrates their knowledge, expertise, and experience in home infusion therapy. We propose a similar provision in new § 424.58(c)(1)(xvi) regarding DMEPOS. Despite the volume of information required per existing § 424.58(b), there is no specific requirement that the AO detail its credentials and experience in the DMEPOS arena. Put otherwise, the current data furnished under § 424.58(b) does not, by itself, give us adequate assurance that the AO understands the intricacies of, for example, the quality standards, DMEPOS enrollment and payment, etc. We believe new § 424.58(c)(1)(xvi) would help remedy this.

(10) Review Timeliness (New § 424.58(c)(xvii))

We propose in new § 424.58(c)(xvii) that the AO furnish information about its ability to conduct timely reviews of supplier accreditation applications. This requirement, which mirrors that in § 488.1010(a)(6)(vii), would help us determine whether the AO has adequate resources to handle the accreditation requests it receives.

(11) Decision-Making Process (New § 424.58(c)(1)(xviii))

Akin to § 488.5(a)(13) concerning certified providers and suppliers, new § 424.58(c)(1)(xviii) would require the AO to describe its decision-making process, including its policies and procedures for approving, denying, or terminating a DMEPOS supplier's accreditation status. This must also include an explanation of the reasons for which the AO will deny or terminate a supplier's accreditation. Since, as already mentioned, accreditation decisions are among the most important AO functions, we must have a full understanding of how the AO will make them. This could help us ascertain, for instance: (1) the criteria the AO will use

in its determinations; (2) how broadly or narrowly the AO interprets the quality standards; and (3) the AO's procedures for notifying a supplier of accreditation approval, denial, or termination.

(12) Surveys (§ 424.58(c)(1)(xix))

We propose in new § 424.58(c)(1)(xix)(A) and (B), respectively, that the AO outlines its policies and procedures for the following:

- Determining whether and when a survey is performed (for example, the DMEPOS supplier is providing a new item type). This must include the circumstances under which the AO will impose a corrective action plan (CAP) in lieu of performing a follow-up survey regarding DMEPOS supplier deficiency.
- Ensuring that all onsite surveys are unannounced, including for preventing unannounced surveys from becoming known to the supplier beforehand.

Given the aforementioned importance of surveys in determining the supplier's compliance with the quality standards, we believe the AO should explain when it will and will not perform a survey. Regarding proposed § 424.58(c)(1)(xix)(B), which parallels § 488.1010(a)(7)(i) for home infusion therapy accreditation, we previously explained the need for surveys to be unannounced. We believe new § 424.58(c)(1)(xix)(B) would help assure us that they will be.

(13) CAPs (§ 424.58(c)(1)(xx))

In lieu of denying or terminating a supplier's accreditation for failing to meet the quality standards, an AO may apply a CAP to the supplier. In general, a CAP permits the supplier to attempt to remedy the problem(s) within a specified timeframe before the AO takes one of these two actions. Existing § 424.58 only references CAPs in paragraph (c)(1)(i) thereof, whereby AOs must provide to CMS various survey-related information, which includes CAPs.

We believe this dearth of CAP provisions in § 424.58 must be addressed. To illustrate, we do not know the following:

- The circumstances under which an AO will impose a CAP and, if a CAP is applied, why the AO chose this approach instead of, as applicable, denial or termination of accreditation.
- The AO's procedures for imposing, monitoring, and terminating a CAP.
- How the AO oversees the supplier's efforts to comply with the CAP and whether a follow-up survey is performed.

- How the AO establishes the CAP's terms (for example, the length of the CAP).

- How the AO ensures that the CAP is adequate to address and correct the deficiencies in question.

- Whether AOs are more inclined to permit CAPs for certain DMEPOS supplier types than for others and whether the supplier's length of enrollment, adverse history (if any), and other factors impact the AO's decision.

We are particularly, though not exclusively, concerned about the first bulleted item. While a CAP (instead of denial or termination) may be justified in some instances if the non-compliance is extremely minor and can be quickly corrected, we have no understanding of the criteria the AO uses in its CAP determinations. In fact, we have received information that, depending on the AO, CAPs are being applied in many instances of non-compliance, even for significant violations of the quality standards. As already noted, compliance with the quality standards is a requirement of § 424.57(c)(24), and non-adherence to any § 424.57(c) supplier standard can result in improper Medicare payments or perhaps grounds for revoking the supplier's Medicare enrollment. If CAPs for such instances of non-compliance are being regularly permitted, we must know the reasons and bases for this. Accordingly, we propose several provisions to enable us to gain a clearer understanding—and, more importantly, to exercise greater oversight—of the AOs' CAP processes. (Additional CAP-related provisions are addressed in section VI.B.2.c.(4). of this proposed rule.)

As part of new § 424.58(c)(1)(xx), and for the foregoing reasons, we propose that the AO outline the policies and procedures via which it will apply a CAP to the supplier. This includes:

- The specific circumstances under which the AO will apply a CAP as opposed to denying or terminating accreditation, and the reason(s) for why the AO believes a CAP in these situations is more appropriate; and
- How a CAP is developed, implemented, and enforced, including—
 - ++ How the AO determines whether a CAP is acceptable;
 - ++ The requirements of (and the timeframe and deadline for) the supplier's resumption of compliance;
 - ++ How the AO ascertains whether the supplier has returned to and maintains compliance; and
 - ++ The circumstances under which the AO will impose a CAP instead of performing a follow-up survey for a supplier deficiency.

(14) Describing and Defining DMEPOS Supplier Deficiencies (New § 424.58(c)(1)(xxi))

We propose in new § 424.58(c)(1)(xxi) that the AO must explain—

- What it considers to be a supplier deficiency and how it defines the term “deficiency”; and
- Whether the AO has different levels of DMEPOS supplier deficiencies.

We are concerned that the meaning of “deficiency” and any AO-identified levels thereof may differ among AOs, resulting in inconsistent determinations. Therefore, we believe we must understand the AO’s policies regarding deficiency classifications.

(15) Potentially Fraudulent Activity (New § 424.58(c)(1)(xxii))

We propose in new § 424.58(c)(1)(xxii) that the AO must describe its processes for: (1) detecting and addressing potential fraud, waste, and abuse by suppliers (including identifying the AO’s definitions of the terms “fraud”, “waste”, and “abuse”); and (2) reporting this conduct to CMS, and, as applicable, law enforcement. While the AO’s principal function under § 424.58 is to perform the accreditation activities described therein, the AO must not disregard possible fraud, waste, or abuse by suppliers. For instance, suppose an AO is performing a survey and discovers that certain records the supplier furnishes to the AO appear to be falsified. We believe the AO should have procedures in place for handling these and other situations and referring them to CMS and, as applicable, law enforcement.

(16) Agreement of Compliance (New § 424.58(c)(1)(xxiii))

(a) Introduction

As part of the AO application process for certified provider and certified supplier accreditation, 42 CFR 488.5 requires the AO to furnish various written acknowledgements stating that the AO will perform certain activities. These include, for example, providing CMS with the following:

- Copies of all survey reports and related information for providers and suppliers seeking Medicare participation.
- Timely notification of when a survey or complaint investigation identifies an immediate jeopardy situation.
- Notification of any proposed changes in the AO’s accreditation program and that it will not implement them without written notice of continued program approval from CMS.

No concomitant requirement to submit acknowledgement statements exists in current § 424.58(b). This is concerning because, in our view, without a written, binding AO commitment to execute functions required under § 424.58, we are less assured the AO will, in fact, do so. Indeed, providers and suppliers enrolling in Medicare must sign a certification statement on their Form CMS–855 application in which they agree to adhere to various requirements, including the Medicare laws, regulations, and program instructions applicable to the provider or supplier. We see no appreciable difference between this certification and one that would require an AO to make similar agreements—a particularly important consideration given that we are entrusting the AOs with the role of confirming DMEPOS suppliers’ compliance with the quality standards. In both cases, millions of Trust Fund dollars could be at stake if we lack confidence in the party’s willingness and readiness to adhere to all Medicare requirements. We accordingly believe that, as in § 488.5, DMEPOS AOs should have to explicitly agree to certain conditions as part of the application process. (We note that some of the requirements in § 424.58(c)(1)(xxiii) would refer to proposed new paragraphs in § 424.58 that will be addressed later in this section of this proposed rule.)

In the opening paragraph of new § 424.58(c)(1)(xxiii), we propose that the AO’s chief executive officer (CEO) (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) provide written acknowledgement that, as a condition of CMS’ approval or continued approval of the AO’s accreditation program, the AO agrees to adhere to the provisions in § 424.58(c)(1)(xxiii). The acknowledgement, which the official must sign and date and which must be on the AO’s letterhead, must list all the data elements in § 424.58(c)(1)(xxiii) and contain the AO’s agreement to comply therewith.

Two matters should be noted regarding this proposal. First, the requirement that the CEO or similar official with binding authority sign the statement is consistent with the provision at § 424.510(d)(3)(1)(C) that an authorized official (as defined in § 424.502) must sign an initial provider enrollment application of behalf of an organization. Second, several of the paragraphs in 42 CFR part 488 require acknowledgement statements as a condition of AO approval. We believe our proposed statements should also apply to reapprovals and continued

approval, particularly the latter. It is not enough for the AO to comply with § 424.58 only upon initial approval and reapproval. We believe the AO should acknowledge that compliance must be constant and that, as discussed further in this proposed rule, a failure to maintain it could result in the termination or suspension of the AO’s approval status.

(b) Data Submission Within 3 Business Days

We propose in new § 424.58(c)(1)(xxiii)(A)(1) and (2), respectively, that the AO must agree to provide CMS within 3 business days of the latter’s request—

- Any of the data described in § 424.58(e)(1)(i); and
- Any other information CMS deems necessary to facilitate its oversight of the AO’s accreditation program.

Concerning (c)(1)(xxiii)(A)(1), AOs are presently required each month under § 424.58(c)(1)(i) (which, as explained later in this proposed rule, will be designated as new paragraph (e)(1)(i)) to furnish CMS with certain information, such as copies of all survey results and CAPs. Considering, again, our role as overseer of Medicare DMEPOS accreditation activities, we must be able to closely and constantly monitor AOs’ activities. Having to wait up to a month to receive copies of survey reports and other survey data is antithetical to this. We believe a 3-business day period would effectively balance our need to secure this data expeditiously and the AO’s need for several days to acquire, organize, and submit the information to us. This does not necessarily mean we will frequently request this information outside of the previously mentioned monthly reports. It only means we reserve the right to ask for it if, in our view, circumstances warrant.

We believe proposed paragraph (c)(1)(xxiii)(A)(2) is especially important. Even with the extensive information submissions we would require in revised § 424.58, this may not capture all the data we need to ensure our effective oversight of the AOs. As the steward of the Medicare Trust Funds, we should be able to collect any additional information required to ascertain whether the AOs are properly executing their respective accreditation programs. We believe the broad scope of paragraph (c)(1)(xxiii)(A)(2) would afford us this flexibility.

(c) Immediate Jeopardy Notifications

We previously noted that existing § 424.58(c)(4) requires the AO to send written notice to CMS within 2 calendar days of identifying an accredited

DMEPOS supplier's deficiency if the latter poses an immediate jeopardy situation; any adverse action the AO accordingly takes must also be identified. Given our obligation to protect Medicare beneficiaries and the consequent need for us to know when their safety may be threatened, we believe that the AO's specific agreement to comply with this requirement (which would be designated as new § 424.58(e)(1)(iii)) is warranted.

(d) Notification of Change in AO Program

Current § 424.58(c)(1)(v) requires an AO to notify CMS on a monthly basis of any proposed changes to its accreditation standards, requirements, or survey process. Any such changes can significantly impact the AO's accreditation program, which, in turn, can affect our responsibility for the DMEPOS accreditation program as a whole. Hence, we propose in new § 424.58(c)(1)(xxiii)(C) that the AO must agree: (1) to furnish this notification to us in writing; and (2) that it will not implement such changes absent prior written notice of continued program approval from CMS consistent with § 424.58(e)(2) (discussed later in this proposed rule).

(e) Termination or Other Change in Supplier's Accreditation Status

Section 488.1010(a)(17)(iv) requires a home infusion therapy supplier AO to acknowledge that it will notify CMS of any decision to revoke or revise the accreditation status of a specific HIT supplier within 3 business days of the date the AO took the action. As accreditation is a requirement for DMEPOS enrollment under § 424.57(c)(24), CMS must know as quickly as possible when a supplier's accreditation is terminated, revoked, withdrawn or amended so we can take similar action concerning the supplier's enrollment; a belated notice from the AO could result in improper payments to an unaccredited supplier. Thus, we propose in new § 424.58(c)(1)(xxiii)(D) that the AO must agree to provide this notification in writing to CMS within 3 business days of the AO's action.

(f) CAP Information

Consistent with our previously mentioned rationale for proposed new § 424.58(c)(1)(xx), we propose in new § 424.58(c)(1)(xxiii)(E) that the AO must agree to inform CMS of any decision to apply a CAP to a specific supplier within 10 calendar days of the decision. This must include—

- The reason for the decision;

- A detailed explanation and justification as to why the AO applied a CAP instead of, as applicable, denying or terminating the supplier's accreditation; and
- The details of the supplier's CAP.

(g) Data for CMS Evaluation of Performance

Section 488.5(a)(11)(ii) requires a certified provider or supplier AO to agree to submit timely, accurate, and complete data to support CMS's evaluation of the AO's performance. Data to be submitted includes, but is not limited to, provider/supplier identifying information, survey schedules and findings, and notices of accreditation decisions; the AO must submit this information according to the instructions and timeframes CMS specifies. This regulatory provision encompasses a wide range of data. Though some of it may overlap other data referenced in proposed new § 424.58(c)(1), we believe a general, overarching agreement to furnish the scope and breadth of data addressed in § 488.5(a)(11)(ii) is justified so we can ensure that we have all information necessary to execute our oversight functions. To this end, new § 424.58(c)(1)(xxiii)(F) would duplicate the requirements of § 488.5(a)(11)(ii) (with modest modifications specific to DMEPOS suppliers).

(h) AO Implementation of CMS Changes

There are instances where CMS changes its DMEPOS accreditation program requirements. Current § 424.58(c)(2) requires that within 30 calendar days of said change, the AO must submit to CMS: (i) an acknowledgment of CMS's notification of the change; (ii) a revised crosswalk reflecting the new requirements; and (iii) an explanation of how it will alter its standards to comply with CMS's new requirements within the timeframes that CMS specifies in notification. As it is important for AOs to implement these changes timely and in full, we believe the AO should explicitly commit to do so. New § 424.58(c)(1)(xxiii)(G) would thus require that the AO agree to adhere to the following:

- Submission of the data required in § 424.58(e)(7). (New paragraph (e)(7) would reflect current requirements in paragraph (c)(2).)
- The proposed changes must be submitted to CMS within 30 calendar days of the date of CMS' written notice to the AO.
- The AO must not implement its proposed corresponding changes without prior CMS approval.

(i) Deficiencies

We previously noted that new § 424.58(c)(1)(xxi) would require the AO to explain what it considers to be a DMEPOS supplier deficiency, how it defines the term, and whether it has different levels of deficiencies. However, and to facilitate consistency among the AOs, we believe CMS should retain the discretion to: (1) define the term deficiency; and (2) establish deficiency levels for use across all AO DMEPOS accreditation programs. New § 424.58(c)(1)(xxiii)(H) would thus require the AO to agree to accept and adhere to any CMS-established deficiency definitions and levels and categories thereof.

(j) Surveyors as Witnesses

Consistent with our aforementioned intention to move current § 424.58(b)(1)(xv) to new § 424.58(c)(1)(xxiii), we propose that new § 424.58(c)(1)(xxiii)(I) would require the AO to agree that its surveyors can serve as witnesses if CMS takes an adverse action against a supplier based on an accreditation finding.

(k) Sampling

We earlier addressed in this proposed rule the concept of sampling, in which the AO utilizes a formula to determine which locations within a particular group should be surveyed. We propose to require the AO's agreement in new § 424.58(c)(1)(xxiii)(J) that if CMS permits the AO to perform surveys via a sampling process, the AO: (1) will submit to CMS its planned sampling methodology in detail; and (2) will not undertake sampling until CMS has approved the AO's methodology. Considering that certain suppliers will be not surveyed under a sampling approach, we must ensure that the AO's methodology aligns with CMS' obligation to protect Medicare beneficiaries and the Trust Funds against non-compliant suppliers.

(l) Patient Records

As part of its survey of a supplier, the AO must examine the supplier's patient medical records. This helps confirm that the supplier is actually serving patients and that the items and services furnished to them are legitimate. For this reason, and as stated in sub-regulatory guidance, the reviewed patient medical records must not include: (1) mock files; (2) fictional patients; (3) simulated documentation;

and (4) templates.⁶⁶ Actual records of the patients are required. With the aforementioned importance of verifying the bona fide provision of these items and services, we propose in new § 424.58(c)(1)(xxiii)(K) that the AO agree not to use these four types of records in its surveys. We also propose to include duplicate patient records as a fifth category. This means that the reviewed records must be of the supplier's own patients and not those of another supplier. We have encountered situations where multiple suppliers within a larger organization have similar patient records. We do not believe that records of other suppliers' patients should be considered in the survey, for they do not reflect the items and services that the surveyed supplier itself is furnishing.

Although we have elected to address this topic via rulemaking in new § 424.58(c)(xxiii)(K), we emphasize that we retain the authority under section 1834(a)(20)(E) of the Act to establish, add, and modify DMEPOS quality standards via sub-regulatory guidance.

(m) Costs of Ad-Hoc Surveys

As discussed further in section VI.B.2.d.(7). of this proposed rule, we are proposing in new § 424.58(e)(8)(ii) that CMS may at any time direct the AO to perform a survey of any accredited supplier or a group thereof. Given this, we are concerned there could be delays in the survey's performance due to a potential disagreement between the AO and the supplier regarding which of them pays the cost of a CMS-required survey. To avoid such situations, we believe the cost issue should be resolved well beforehand. Accordingly, we propose in new § 424.58(c)(xxiii)(L) that the AO must agree to have a binding written agreement with each supplier it accredits regarding whether the AO, the supplier, or both will assume the costs of a survey that CMS directs the AO to perform under paragraph (e)(8)(ii) of this section.

(n) Truthfulness and Accuracy

To ensure that the AO understands its obligation to submit accurate and complete data to CMS at all times, we propose in new § 424.58(c)(xxiii)(M) that the AO must agree to submit all required information to CMS both before and after approval of its accreditation program in a truthful, accurate, and complete manner.

(o) Compliance With § 424.58

In general, the components of our proposed § 424.58(c)(1)(xxiii) AO attestation statement address fairly specific elements (for example, an attestation to utilize CMS's deficiency definition). Yet we reiterate that adherence to all provisions in § 424.58 is still required. Merely because § 424.58(c)(1)(xxiii) is silent regarding a certain provision in § 424.58 should not, in our view, exempt the AO from agreeing to comply therewith. Consequently, we propose in § 424.58(c)(1)(xxiii)(N) that the AO in its statement must agree to comply with all of the requirements in § 424.58 at all times. We note this would include agreeing to adhere to the policies, procedures, and practices it outlined under § 424.58(c) as part of its initial or reapproval application and any changes thereto made with prior CMS approval. In making its decision whether to approve or reapprove an AO's accreditation program, CMS relies upon the explanations the AO furnished in the application. Furthermore, in approving any change to an AO's policies, procedures, and practices, CMS does so with understanding that the AO will adhere to the new processes. We therefore believe the AO should abide by: (1) its representations in its application; and (2) any policy, procedural, or practice change that CMS authorized.

(17) Additional Information Needed (New § 424.58(c)(2))

Despite the wide scope of data to be furnished per § 424.58(c)(1), CMS may need additional information to fully assess the AO's credentials. Thus, we propose in new § 424.58(c)(2) that if CMS determines that further data is necessary to make a determination on the AO's request for approval, we would notify the organization and afford it an opportunity to provide this data.

(18) Application Withdrawal (New § 424.58(c)(3))

Similar to § 488.1010(c) with respect to AO applications for HIT supplier accreditation, we propose in new § 424.58(c)(3) that an AO may withdraw its application for approval of its accreditation program at any time before CMS posts the approval described in § 424.58(c)(5) (discussed in section VI.B.2.(b).(20). of this proposed rule). This would give the AO adequate opportunity to withdraw its application if it wishes while setting forth a specific withdrawal deadline.

(19) Reasons for Denial

Section 424.530(a) lists 18 reasons for which CMS can deny provider or supplier enrollment applications, including those from DMEPOS suppliers. Among these grounds are the following as outlined in § 424.530(a)(1) through (4) and (12)(i), respectively:

- The provider or supplier is non-compliant with the enrollment requirements in Title 42.
- The provider or supplier or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, of the provider or supplier is—

++ Excluded by the OIG from Medicare, Medicaid, and any other Federal health care program; or

++ Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

- The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

- The provider or supplier has submitted false or misleading information on the enrollment application to become Medicare-enrolled.

- The provider or supplier is terminated, revoked or otherwise barred from participation in a State Medicaid program or any other Federal health care program.

The central purpose of these provisions is to prevent non-compliant and unqualified providers and suppliers—or those that present a program integrity risk—from being eligible to receive Medicare payments. While DMEPOS AOs, unlike DMEPOS suppliers, neither enroll in Medicare nor receive Medicare payments, they are responsible for ascertaining quality standard compliance for potentially hundreds of suppliers that may or do bill Medicare. In other words, in general contrast to a single supplier, an AO's qualifications and performance can impact the payment of hundreds of millions of Medicare dollars. Consequently, considering the likely greater effect an AO has on the Trust

⁶⁶ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html>.

Funds, we believe it is especially important to have clear reasons in § 424.58 for which we can deny an AO's application for approval of its accreditation program.

We propose the following denial reasons in new paragraphs (c)(4)(i) through (viii), several of which duplicate those in § 424.530(a), given the latter's effectiveness in keeping unqualified providers and suppliers out of the Medicare program. Specifically, denial of an AO's application can occur if CMS determines that—

- *The AO has failed to comply with all application, data, and agreement submission requirements outlined in § 424.58(c).* In our view, if the applicant does not submit all the required information and agreements in § 424.58(c), the application is deficient, and the AO therefore cannot be approved.

- *The AO has failed to provide reasonable assurance (as defined in paragraph (b)).* CMS must have confidence that the AO's accreditation program will comply with all applicable CMS requirements and, above all, ensure that only qualified DMEPOS suppliers are accredited.

- *The current number of CMS-approved DMEPOS AOs is sufficient to ensure the continued administration of CMS' DMEPOS accreditation program.* We believe that limiting the number of DMEPOS AOs would allow us to exercise closer scrutiny of each AO because there would be fewer to oversee.

- *The AO's DMEPOS program was previously terminated, suspended, or placed on probation by CMS under, respectively, new § 424.58(h), (i), or (j).* As explained further in this section VI.B.2. of this proposed rule, we are proposing that CMS may terminate, suspend, or place on probation an AO's accreditation program in certain circumstances, such as non-compliance with the provisions of § 424.58. In light of the significance of such a CMS action, we do not believe we should be required to approve an AO's accreditation program that was previously found to be deficient in some manner.

The fifth and sixth denial reasons are akin to, respectively, those in previously referenced §§ 424.530(a)(2), (3) and (12) as well as § 424.530(a)(4). (The fifth also includes types of actions in our current definition of "final adverse action" in § 424.502 (for example, revocation of Medicare enrollment).) These are intended to help ensure that neither the AO nor certain entities or individuals closely associated therewith pose program integrity risks.

- The AO, or any owner (as defined in § 424.502), managing employee (as defined in § 424.502), governing board member, W-2 or contracted surveyor, or W-2 or contracted health care or administrative or management services personnel thereof—

- ++ Is OIG excluded;

- ++ Is debarred, suspended, or otherwise excluded from participating in any Federal procurement or non-procurement activity; or

- ++ Within the preceding 10 years:

- ++ Was convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries;

- ++ Has had a Medicare enrollment revoked under § 424.535;

- ++ Has had a license to provide health care suspended or revoked by any State licensing authority; or

- ++ Has been suspended or terminated from participating in a Federal or State health care program.

- *The AO has submitted false or misleading information on its application in order to gain CMS approval or reapproval as a DMEPOS AO.* The submission of false or misleading information on an AO's application raises serious doubts that the AO can be a reliable partner of the Medicare program, hence the need for this denial reason.

Our proposed seventh and eight denial reasons are as follows:

- The AO is non-compliant with any provision in § 424.58.

- *CMS otherwise determines that approval of the applicant as a DMEPOS AO would not be in the best interests of the Medicare program and its beneficiaries.* (This "best interests" principle is similar to that in previously referenced § 424.530(a)(3).)

The proposed non-compliance denial reason is based on aforementioned § 424.530(a)(1), and we believe it should be an obvious basis for denial. If the entity cannot demonstrate adherence to all provisions of § 424.58, this raises real questions as to whether it can be an effective DMEPOS AO. Regarding the "best interests" ground, there could be isolated instances situations where none of the other proposed denial reasons apply but CMS nonetheless has concerns about how the entity might perform as a DMEPOS AO. Consider this brief, non-exhaustive list of possible examples:

- CMS receives information indicating that the entity—while acting as an AO or as a CMS contractor in another capacity—performed in what CMS believes was a sub-standard manner.

- Past or present feedback from stakeholder groups generates doubts about the prospective AO's capabilities.

- In reviewing the entity's otherwise complete application, CMS concludes, for instance, that:

- ++ Some of the AO's surveyor personnel are insufficiently experienced in the DMEPOS arena.

- ++ The AO's stated policies for avoiding conflicts of interest are inadequate.

- ++ The AO will too frequently apply a CAP to a non-compliant supplier instead of terminating its accreditation.

We recognize that this eighth denial reason (which would constitute proposed paragraph (c)(4)(viii)) could in certain situations overlap with one or more other denial reasons. To illustrate, a prospective AO could fail to provide reasonable assurance (proposed (c)(4)(ii)) based on its non-compliance with several provisions of § 424.58 (proposed (c)(4)(vii)), which accordingly indicates that approving the AO would not be in the best interests of Medicare and its beneficiaries (proposed (c)(4)(viii)). Yet there are a wide range of possible situations where we might have concerns about a particular initially applying or reapplying AO but said scenario is not explicitly addressed in the other denial reasons. We believe proposed (c)(4)(viii) is necessary to account for such cases. As already explained, we have an obligation to protect the Trust Funds from improper payments and Medicare beneficiaries from potential harm, and we therefore do not believe we should be required to approve an AO—even if it is otherwise compliant with § 424.58—if doing so would not be in Medicare's best interests.

(20) Notice of Approval/Denial, Public Notice, and Length of Approval (New § 424.58(c)(5) Through (7))

Existing § 424.58 does not address when and how an AO is notified of CMS' decision to approve or deny its application for approval of its accreditation program. To clarify these issues, we propose to incorporate several procedures in §§ 488.1010(d) and 488.1020 within new § 424.58(c)(5) and (6), respectively. Under § 424.58(c)(5), CMS would send notice of its decision to the AO within 210 calendar days from the date CMS determines that the AO's application is complete. The notice would include: (i) the basis for the decision; (ii) if applicable, the effective date of approval; and (iii) if applicable, the length of the approval (not to exceed 6 years). Under proposed new § 424.58(c)(6), CMS would announce on

its website its decision to approve or deny the application. This announcement would be posted within 210 calendar days from the date that CMS determines that the AO's application was complete. If the application is approved, the posting would also state the approval's effective date (no later than the notice's publication date) and length (6 years or less).

Three things must be emphasized with respect to these proposals.

First, the procedures in § 488.1020 regarding HIT accreditation are largely similar to those in § 488.5(e)(2) concerning certified provider/supplier accreditation. Hence, there is a well-established, effective CMS process for announcing AO application decisions. In general, we see no reason to alter this process for DMEPOS accreditation. However, unlike with § 488.1020 and § 488.5(e)(2), we are proposing to publish our decision on our website rather than in the **Federal Register**. We believe this would allow us to more quickly notify stakeholders of this determination.

Second, the 210-day timeframe is necessary because we must have adequate time to carefully and thoroughly review all AO applications (and the detailed information furnished therewith). AOs, as noted, have an indispensable role in confirming that DMEPOS suppliers are compliant with the quality standards, and we must ensure that the applying AO has the ability to perform this task.

Third, the maximum period of an AO DMEPOS program's approval would be 6 years. We stress that this would not mean each program would be approved for 6 years, or even 4 or 5. Approval could be for any length of time within that range that CMS deems appropriate. There could be circumstances where, for instance, CMS approves a particular AO's program but only for a fairly short period to assess the AO's performance before—, if the AO seeks reapproval—potentially committing to a longer timeframe. To make clear CMS' discretion in this regard, we propose in new § 424.58(c)(7) that CMS may approve an accreditation program for any period up to a maximum of 6 years.

3. AO Reapproval Process (New § 424.58(d))

New § 424.58(d) would outline the procedures involving an AO's application for reapproval of its DMEPOS accreditation program. As previously mentioned, and except as otherwise noted, these procedures would generally duplicate those for

initial applications in terms of content and rationale.

We propose in new § 424.58(d)(1)(i) that except as stated in paragraph (d)(1)(ii), an approved DMEPOS AO that seeks to continue as such must apply for reapproval of accreditation at least 9 months before its current approval term expires. We believe the earliest possible reapproval application submission is needed to afford CMS—prior to the current approval's expiration—sufficient time to: (1) review the application; (2) consider the AO's past performance; and (3) render a decision. We also propose in paragraph § 424.58(d)(1)(i), however, to have the discretion to grant the AO an additional 30 days to reapply. This would enable us to address situations where, for instance, the AO wishes to reapply but needs more time to finalize its submission.

We previously noted our concern that we have not reapproved any AO since the DMEPOS accreditation program's inception in 2006. Considering this nearly two-decade period, we believe it is imperative to commence a reapproval process for all current AOs as soon as possible after the effective date of any finalization of our proposals. Therefore, we propose in § 424.58(d)(1)(ii) that CMS may require AOs to submit reapproval applications under paragraph (d) any time after January 1, 2026, which would be the effective date of our revisions to §§ 424.57 and 424.58. The application would have to be submitted within 60 calendar days of CMS' submission request; if it is not, CMS terminates the AO's DMEPOS accreditation approval. This would afford the AO adequate time to prepare its application without unduly delaying our AO reapproval initiative described in § 424.58(d)(1)(ii). At the same time, we believe this deadline must be met so that the AO does not indefinitely retain its status pending the completion of the general reapproval process. If the AO wishes to continue its DMEPOS accrediting status, it must comply with all requirements in § 424.58, including proposed paragraph (d)(1)'s 60-day timeframe.

We propose in new § 424.58(d)(2) that as part of its reapproval application submission: (1) the AO would have to furnish all information and statements identified in § 424.58(c)(1); and (2) CMS could request additional information under § 424.58(c)(2). This is to ensure that CMS would have enough data on hand to make its determination and secure the important AO agreements specified in § 424.58(c)(1)(xxiii).

Furthermore, we propose in new § 424.58(d)(3) through (7) to duplicate

our proposals in § 424.58(c)(3) through (7), respectively. The same rationales would apply—namely, to: (i) establish clear reapproval application withdrawal procedures; (ii) to protect the Trust Funds against non-compliant AOs and potential program integrity risks; (iii) give CMS adequate time (a maximum of 210 days) to render its decision; and (iv) reiterate CMS' discretion regarding the length of the approval period.

4. Ongoing Responsibilities of a CMS-Approved AO (New § 424.58(e))

Existing § 424.58(c)(1) through (6) outline activities an approved AO must undertake on an ongoing basis. These functions, some of which have already been mentioned, are respectively:

- Monthly submission of data concerning the AO's activities (for example, copies of surveys; notice of accreditation decisions and complaints received; information about actions taken against suppliers, etc.).
- Submission of the acknowledgment, cross walk, and explanation in response to a change in CMS requirements.
- Allowing the AOs' surveyors to serve as witnesses if CMS takes an adverse action against a supplier based on an accreditation determination.
- Notification to CMS within 2 calendar days of a supplier's immediate jeopardy deficiency.
- Within 10 calendar days of receiving CMS notice that CMS intends to withdraw the AO's approval, provide written notice of the withdrawal to all the AO's accredited DMEPOS suppliers.
- Annually furnish CMS-specified summary information regarding the prior year's accreditation activities and trends.

These requirements would be included within new § 424.58(e). However, and as further explained, we also propose certain changes to them.

a. Submission of Monthly Information, Requested Information, and Immediate Jeopardy Deficiencies (New § 424.58(e)(1))

There are five categories of data in current § 424.58(c)(1)(i) through (v) that the AO must furnish on a monthly basis. We propose several revisions thereto.

First, in the opening paragraph of (c)(1) (which we are redesignating as new paragraph (e)(1)(i)), we propose to change the reference “on a monthly basis” to “no later than the last day of each month.” We believe the latter is clearer in terms of when the deadline for monthly submission is.

Second, existing paragraph (c)(1)(i) requires monthly submission of copies of all accreditation surveys, together with any survey-related information that

CMS may require (including CAPs and summaries of findings with respect to unmet CMS requirements). Paragraph (c)(1)(i) would become new paragraph (e)(1)(i)(A), with the parenthetical in the previous sentence regarding CAPs and summaries constituting new paragraph (e)(1)(i)(A)(1). In new § 424.58(e)(1)(i)(A)(2), and for the same reason behind proposed new § 424.58(c)(1)(iii)(G), we propose that the required data must include the instances in which the AO had the discretion to perform a survey but elected not to, including the reason(s) behind the AO's decision.

Third, we propose to delete the requirement in current § 424.58(c)(1)(iii) of monthly notice to CMS regarding complaints. This is because we are proposing in new § 424.58(e)(3)—as discussed in section VI.B.2.d.(3). of this proposed rule—a separate process and timeframe for the AO's submission of complaint data to CMS.

Fourth, we propose to add new paragraph (e)(1)(i)(C) that would require monthly notice of resolved deficiencies. As already mentioned, any DMEPOS supplier deficiency—even if it has been resolved and regardless of whether it invoked immediate jeopardy considerations—is of concern to us since it involves non-compliance with the quality standards or other applicable CMS requirement. Hence, we believe CMS should be made aware of them.

We are not proposing to change the basic content of existing paragraphs (c)(1)(ii) and (iv) regarding, respectively, the monthly reporting of accreditation decisions and adverse actions. These two provisions, with slight technical modifications, would serve as new paragraphs (e)(1)(i)(B) and (D), respectively.

Current § 424.58(c)(1)(v) requires the AO to report proposed changes in its accreditation standards or requirements or survey process on a monthly basis. It also states that CMS may withdraw its approval of the AO's accreditation program if the AO implements these changes without prior CMS approval. We are proposing to delete this requirement because, as discussed in section VI.B.2.d.(2). of this proposed rule, the question of AO process and standard changes will be addressed more thoroughly in new § 424.58(e)(2).

In new § 424.58(e)(1)(ii), we propose that—

- CMS may at any time request the AO to submit any of the information described in new paragraph (e)(1)(i) or any other data CMS deems necessary to facilitate its oversight of the AO's accreditation program; and

- The AO must furnish this data to CMS within 3 business days of the request.

We noted in our discussion of proposed § 424.58(c)(1)(xxiii)(A) our concern about not receiving data that could be critical to our oversight responsibilities for several weeks after our request. We must be able to obtain this information much sooner if circumstances warrant, thus the need for § 424.58(e)(1)(ii).

We also previously discussed current § 424.58(c)(4) and its 2-day notification requirement regarding immediate jeopardy deficiencies. We propose to retain this requirement as part of new § 424.58(e)(1)(iii).

b. AO Standard or Requirement Changes (New § 424.58(e)(2))

As mentioned earlier, existing § 424.58(c)(1)(v) requires the AO each month to notify CMS of any proposed changes to its accreditation standards, requirements, or survey process; the AO cannot implement the change without prior CMS approval. Given our responsibility for ensuring that suppliers meet all accreditation requirements and comply with the quality standards, it is imperative that we: (1) be made aware of changes in how an AO accredits suppliers; and (2) have the authority to either authorize or prohibit the AO's proposed revision. To illustrate, it would be very problematic if an AO changes its requirements without our knowledge such that it became easier for a potentially non-compliant supplier to become accredited. For this reason, we are not proposing to revise the basic requirements of § 424.58(c)(1)(v). Yet we believe that additional safeguards are needed so that we: (1) become aware of planned changes earlier than we presently do; and (2) have enough information to fully understand the breath of the revision. We therefore propose several changes to § 424.58(c)(1)(v), which would become new § 424.58(e)(2).

First, we propose in the opening paragraph of § 424.58(e)(2) to incorporate the existing notice requirement in current § 424.58(c)(1)(v) with two additions. One addition would require the notice to be written. This is current practice, but we wish to include this in regulation. The other would state that the scope of § 424.58(e)(2) includes the addition, modification, or removal of a DMEPOS product service category to the list of categories for which the AO accredits DMEPOS suppliers. We have received questions from AOs as to whether such changes, per current § 424.58(c)(1)(v), require prior CMS

approval. To confirm that they do, we believe this addition is necessary.

Second, new § 424.58(e)(2)(i) would require the AO to submit the notice at least 60 calendar days before the proposed change's intended effective date. Paragraphs (e)(2)(i)(A) and (B) would also require, respectively, the notice to include—

- A detailed explanation of the revisions and the rationale for them; and
- A detailed crosswalk (in table format) containing the exact language of the AO's revised accreditation requirements and the applicable Medicare requirements for each.

We believe these changes would help ensure that we receive adequate advance notice of, and sufficient information regarding, the proposed changes.

In new § 424.58(e)(2)(ii), we propose that CMS would furnish the AO written approval or disapproval of the proposed change within 30 calendar days of the revision's effective date. This provision would clarify for the AO what it can expect regarding the timing of CMS' decision.

In new § 424.58(e)(2)(iii), we propose to largely restate the existing policy in § 424.58(c)(1)(v) that CMS may terminate or suspend its approval of the AO if the latter implements the change before or without CMS approval. This would emphasize to the AO the need for prior CMS acquiescence to the revision.

c. Complaints (New § 424.58(e)(3))

We previously noted that existing § 424.58(c)(1)(iii) requires the AO to provide monthly notice to CMS of all complaints involving suppliers. As with certain other information falling under current § 424.58(c)(1), we are concerned that only requiring the reporting of complaints on a monthly basis could leave us unaware for weeks of allegations of suppliers' non-compliance with the quality standards or other applicable CMS requirement. Again, considering our obligation to safeguard the Trust Funds against improper payments and to protect beneficiaries, we believe complaint data should be furnished to us more frequently. We accordingly propose the following requirements in new § 424.58(e)(3).

In paragraphs (e)(3)(i)(A) through (C), we propose that upon receipt of a complaint, the AO must, respectively—

- Provide written notice of the complaint to CMS no later than 5 calendar days after receipt;
- In accordance with its existing policies and procedures, perform an initial review of the complaint to determine whether, based on the complaint and any other data, the

supplier may be non-adherent to one or more quality standards or other applicable CMS requirement; and

- Within 21 days after receiving the complaint, conduct a survey of the supplier if the initial review determines that such non-compliance may exist.

Paragraph (e)(3)(i)(A) would ensure that we receive the complaint expeditiously. The requirements in paragraph (e)(3)(i)(B) would help the AO assess the validity of the complaint, while the survey under paragraph (e)(3)(i)(C) would confirm said validity if evidence of non-compliance exists. We believe that having a standardized notification and investigative process would: (1) clarify CMS' expectations for handling complaints; and (2) allow for each complaint to be thoroughly considered and vetted before any action is taken against the supplier.

To also ensure that CMS is notified not only of the complaint itself but also the AO's determination on the matter, we propose new § 424.58(e)(3)(ii). This would require the AO—at least 10 calendar days after completing the action in, as applicable, paragraph (e)(3)(i)(B) or (C)—to give CMS written notice of the result of the initial review or, as applicable, the survey. Too, the notice must inform CMS of any action the AO took or intends to take regarding the supplier, such as a termination of accreditation or imposition of a CAP.

d. CAPs (New § 424.58(e)(4))

Although proposed § 424.58(c)(1)(xx) requires the AO during the application process to describe the policies and procedures it would use to decide whether to impose a CAP, it does not require the AO to notify CMS of specific instances where a CAP was indeed imposed, including when done in lieu of denying or terminating the supplier's accreditation. We believe such notification is important so we can ascertain the AO's: (1) compliance with the CAP policies contained in its application for CMS approval or reapproval; and (2) judgment in imposing CAPs instead of denying or terminating accreditation. To this end, we propose in the opening paragraph of new § 424.58(e)(4) that the AO must give CMS written notice of any decision to apply a CAP to a particular supplier no later than 10 calendar days after its decision. The notice must include—

- The reason for the decision;
- A detailed explanation and justification as to why the AO imposed a CAP instead of, as applicable, denying or terminating the supplier's accreditation; and
- The terms of the supplier's CAP (for example, deadline for compliance, the

AO's plans for enforcement and ensuring compliance).

These three requirements would be designated as new § 424.58(e)(4)(i), (ii), and (iii), respectively.

e. Accreditation Denials and Terminations (New § 424.58(e)(5))

We propose in new § 424.58(e)(5)(i) that the AO must give CMS written notice of any decision to deny, terminate, revoke, withdraw, or amend a supplier's accreditation within 5 calendar days of the decision; the notice must identify the reason for the AO's determination. Knowledge of supplier denials, terminations, etc. is no less important for us than our awareness of other AO matters, such as CAPs and complaints. Indeed, this information could help CMS detect potentially systemic issues and trends among suppliers. For instance, suppose the data indicates that a substantial number of prospective suppliers failed to comply with Quality Standards X, Y, and Z. In response, CMS could focus part of its DMEPOS supplier program integrity efforts on ensuring that currently accredited suppliers are adhering to X, Y, and Z, perhaps by requesting an AO to perform ad-hoc surveys of certain suppliers that are limited to these three quality standards.

While we believe this proposed rule would improve the DMEPOS accreditation program by, in part, strengthening and enhancing the requirements with which AOs must comply, we recognize the relative independence that AOs must retain in their operations and particularly their accreditation decision-making. We can establish regulatory parameters for the AO process, but the AO, rather than CMS, is regularly on-site verifying suppliers' quality standard compliance. We therefore must often defer to the AO's judgment on these matters to the extent that: (1) the AO's decision was consistent with CMS regulations and policies; and (2) we are satisfied with the AO's rationale for the decision. Nonetheless, there are several situations where we believe we must require that the AO take action because of the serious program integrity risk the situation entails. Although any supplier that is non-compliant with certain quality standards is of concern to us, more concerning is if the supplier is not even at the location it claims to be, is not operational, is unlicensed, or cannot be accessed. All these situations raise the possibility that the supplier could be an illegitimate operation, a situation we have repeatedly seen over the years with DMEPOS suppliers. At a minimum, they represent clear cases where compliance

with the quality standards would be impossible and could not be remedied by a CAP, given the fundamental defects in the supplier's qualifications.

For these reasons, we propose in new paragraphs (e)(5)(ii)(A)(1) through (5), respectively, that notwithstanding any other provision in § 424.58, an AO must deny or terminate a supplier's accreditation if—

- The supplier fails to meet the licensure requirements in § 424.57(c)(1)(ii);
- The supplier is not operational (as that term is defined in § 424.502);
- The supplier's location fails to meet the accessibility requirements in § 424.57(c)(7)(i)(B);
- The supplier's Medicare enrollment is revoked due to non-compliance with one or more DMEPOS quality standards and the reenrollment bar under § 424.535(c) has not expired; or
- Directed by CMS.

We emphasize that proposed paragraph (e)(5)(ii)(A)(5) would only be utilized in isolated instances considering, again, the AO's general discretion in its decisions. This would mostly, though not exclusively, occur if CMS obtains information—to which the AO may not have been privy—that the DMEPOS supplier is non-compliant with the quality standards and accordingly revokes the supplier's Medicare enrollment. Another, less frequent situation could be if CMS learns that the supplier is engaging in fraudulent conduct; such a supplier obviously should not be accredited. In short, CMS under paragraph (e)(5)(ii)(A)(5) would not direct AO decisions as a matter of course but strictly in exceptional circumstances. To ensure that the AO nonetheless carries out a CMS-directed accreditation denial or termination, we propose in new paragraph (e)(5)(ii)(B) that the AO must: (1) deny or terminate the supplier's accreditation within 3 business days after receiving written notice from CMS to do so; and (2) provide CMS written notice that it has taken this action within 5 business days of receiving the written direction from CMS.

f. Annual Summary of Data and CMS Changes (New § 424.58(e)(6) and (7))

Current § 424.58(c)(6) requires the AO to provide, on an annual basis, summary data specified by CMS that relates to the past year's accreditation activities and trends. Although we are not proposing to change this requirement, we propose to designate it as new § 424.58(e)(6).

We previously noted that as part of the AO statement that proposed § 424.58(c)(1)(xxiii) would require, the AO per § 424.58(c)(1)(xxiii)(G) must—in

response to CMS notification of a change in the quality standards, survey process, or other requirement—furnish CMS with corresponding changes in the AO's requirements. We propose in new § 424.58(e)(7) to outline the required timeframe and content of this data submission.

The opening paragraph of § 424.58(e)(7)(i) would: (1) include the requirement in proposed § 424.58(c)(1)(xxiii)(G); (2) state that the AO's submission of concomitant revisions is to ensure continued comparability with the quality standards, survey process, and other requirements; and (3) require the AO to report its proposed changes to CMS no later than 30 days after receiving CMS' written notice. In addition, new paragraphs (e)(7)(i)(A) through (C) would include the data submission elements and formats required in existing § 424.58(c)(2), specifically—

- An acknowledgment of CMS's notification of the change;
- A revised crosswalk reflecting the new requirements; and
- An explanation of how the AO will modify its standards to conform to CMS's new requirements within the timeframes outlined in the notice it received from CMS.

In new § 424.58(e)(7)(ii), we would state that the AO cannot implement its proposed corresponding revisions without CMS approval. This requirement would help CMS ensure that the AO understands and accurately implements CMS' revisions.

g. Performance of Surveys (New § 424.58(e)(8))

As already noted, not every supplier receives an accreditation survey. For instance, CMS currently permits AOs to undertake sampling for large supplier chain surveys. Factors an AO considers in determining which chain locations are surveyed include: (1) the supplier's physical location (for instance, whether it is in a high-fraud area); and (2) the types of products the supplier furnishes.

We have received information that various DMEPOS suppliers that were not surveyed were later found to be non-compliant with the quality standards and other CMS requirements. We have emphasized throughout section VI.B. of this proposed rule CMS' obligation to prevent improper Medicare payments and to protect beneficiaries. By permitting AOs to forgo surveys in certain instances, we risk the potential for patient harm and for millions of Medicare dollars to be paid to non-compliant suppliers. It is possible that considerable monies over the years have been paid to such parties and that, to

the extent it indeed occurred, this could have been avoided had a survey been conducted. Therefore, we believe we must revisit the current process and establish in regulation stricter and broader requirements regarding the performance of surveys. Consequently, we propose the following requirements in new § 424.58(e)(8).

Proposed opening paragraph (e)(8) and paragraph (e)(8)(i)(A) would state, respectively, that except as otherwise directed or permitted in writing by CMS (for instance, allowing sampling), the AO must perform a survey of all supplier locations for which the supplier seeks accreditation or reaccreditation with the AO. (This includes, but is not limited to, accreditations: (1) for a new item type the supplier has not previously furnished; or (2) as required under 42 CFR 424.551, discussed later in this section of VI.B. of this proposed rule.) Per our concerns about non-surveyed suppliers, we believe the blanket survey requirement in paragraph (e)(8)(i)(A) is necessary. Nevertheless, we also recognize that isolated and limited instances of sampling or other survey exemptions could be warranted. While we are unable to specify or predict in this proposed rule what those instances may be and do not commit to allowing survey exceptions, we believe our administration of the DMEPOS accreditation program requires that we have the flexibility to address particular circumstances as they arise.

New paragraph (e)(8)(i)(B) would require the AO to perform all surveys as unannounced surveys. While the caveat in proposed opening paragraph of (e)(8)(i) would permit us to waive this requirement in certain situations, we do not anticipate doing so given the previously noted importance of preventing prior notice to the supplier.

In new paragraph (e)(8)(i)(C), we propose that the AO cannot accredit the supplier location before: (1) the survey is conducted; and (2) the AO deems the supplier compliant with the quality standards. As stated, the survey's purpose is to confirm this adherence. If we permitted accreditation prior to both the survey and the AO's finding that compliance exists and the supplier accordingly billed Medicare, many thousands of dollars in improper payments could result. To avoid this, we believe paragraph (e)(8)(i)(C) is necessary.

We also propose in new paragraph (e)(8)(ii) that CMS may, at any time, direct the AO to perform a survey of an accredited supplier or a group thereof. We do not believe surveys should be restricted to initial accreditation and re-

accreditation situations, especially considering the aforementioned 3-year time gap between them. Suppliers must at all times be compliant with the quality standards and not merely upon initial accreditation and reaccreditation. To help verify that such adherence is consistently maintained, we believe we need discretion to direct an AO to conduct a survey at any given time. Having to wait until reaccreditation to resurvey the supplier could lead in the interim to improper payments to a supplier that has fallen out of adherence to the quality standards. Moreover, this discretion should not be limited to cases of an actual or suspected supplier deficiency, a matter we also propose to include in paragraph (e)(8)(ii). For example, assume a particular supplier is located in a high-fraud geographic area or had prior (but since resolved) compliance issues. We must have the authority to exercise closer scrutiny of the supplier through a survey if, in our view, the circumstances warrant it.

We further propose in new paragraph (e)(8)(iii) that when performing a survey, the AO must also confirm that the supplier is licensed in accordance with § 424.57(c). Although we believe most AOs perform this task during the survey, we seek to require this in regulation considering the importance of the supplier's compliance with State (and not only Federal) laws.

h. Surveyor Witnesses (New § 424.58(e)(9))

We have cited current requirements in § 424.58(c)(3) that the AO allow its surveyors to serve as witnesses if CMS undertakes an adverse action against a supplier in response to an accreditation finding. Consistent with our reorganization of § 424.58, we propose to designate this requirement without change as new paragraph § 424.58(e)(9).

i. Entrance of Data Into System (New § 424.58(e)(10))

Notwithstanding our proposed additional reporting requirements, we remain concerned about our ability to access accreditation and survey data immediately. There could be instances where we need prompt information about a particular supplier and cannot wait for the AO to send it to us. To illustrate, we may receive data indicating that a supplier may be out of adherence to a particular standard in § 424.57(c), meaning that improper payments are potentially being made to a non-compliant supplier. To assist in our review of this matter and, if non-compliance is found, to take action against the supplier and halt the payments as quickly as possible, real-

time information about the supplier's accreditation history, survey results, deficiencies, CAPs, etc., would be of assistance; indeed, such data could indicate past problems with this supplier. Real-time information would also allow us to detect trends and patterns in supplier accreditations, which, in turn, could help us rapidly implement changes to accreditation practices and procedures, direct the performance of surveys, and take other steps necessary to protect the Trust Funds. Perhaps most importantly, up-to-date information would help ensure that payments to DMEPOS suppliers are accurately made; for example, the sooner we learn through system access of a supplier's termination of accreditation, the sooner we can revoke the supplier and stop payments. In sum, our aforementioned role in preventing improper payments requires us to have immediate access to data that can assist us in this regard.

For these reasons, we propose in new § 424.58(e)(10) that if directed by CMS, the AO must enter accreditation, survey, product code, and other data into a CMS-designated system. This system, to which CMS and the NPEs would have access, would enable us to review accreditation data at any time. To preserve our operational flexibility, we are not outlining in this proposed rule either the specific system involved or the timing, content, and exact extent of the data entry. We may even later determine that the data entry is unnecessary if an alternative means of accessing this information in real-time is established. The implementation of § 424.58(c)(10) is thus contingent upon CMS determining that the entry is needed, hence the "if directed" caveat at the beginning of paragraph (c)(10).

j. Adverse Actions (New § 424.58(e)(11))

We proposed under new § 424.58(c)(4)(v) that CMS could deny an AO's application for approval or reapproval of its accreditation program if the AO, or any AO owner, managing employee, governing body member, surveyor, or health care or administrative or management services personnel has any of the adverse actions specified in § 424.58(c)(4)(v). We propose in new § 424.58(e)(11) to duplicate this denial reason as a general prohibition against such relationships on an ongoing basis, not simply as part of the AO's application determination. We believe this would further underscore the importance of ensuring that parties associated with the AO do not pose program integrity risks.

5. Continuing Federal Oversight of AOs (New § 424.58(f))

Existing § 424.58(d) outlines procedures for our ongoing review of AOs. While we intend to retain some of the provisions of this section, which would become new § 424.58(f), we believe changes to parts of its contents and structure are necessary to improve clarity and strengthen our oversight.

The opening paragraph of current § 424.58(d) states that the paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved DMEPOS AO. We propose to revise this to state that CMS evaluates the performance of each CMS-approved DMEPOS accreditation program on an ongoing basis; means of monitoring include, but are not limited to, the reviews identified in such paragraph (f). We believe this new language would clarify that CMS' oversight procedures are not restricted to those in paragraph (f). Also, as explained in section VI.B.2.f. of this proposed rule, the current § 424.58(d) regarding terminations of AOs will be in proposed new paragraph (h). Hence, the designation of § 424.58(d) as new § 424.58(f) will not include these paragraphs or any other reference to AO terminations.

a. Equivalency Reviews (New § 424.58(f)(1))

As described in current § 424.58(d), an equivalency review involves our comparison of the AO's standards (and the AO's application and enforcement thereof) to CMS requirements and processes. Paragraphs (d)(1)(i) through (iii) outline the following instances in which CMS may perform this review: (i) CMS imposes new requirements or changes in its survey process; (ii) the AO proposes new standards or changes in its survey process; or (iii) the AO's term of accreditation expires. We believe that retaining these three paragraphs in new paragraph (f)(1) would imply that we can only perform equivalency reviews in these three situations, which is not our intention. For reasons already noted, we must be able to constantly monitor the AO's operations—even if none of the three previous scenarios apply—and equivalency reviews are an important means of doing so. Consequently, we propose in new paragraph (f)(1) that we may perform an equivalency review at any time; the contingencies in existing (d)(1)(i) through (iii) would not be included in paragraph (f)(1).

b. Validation Survey of Suppliers (New § 424.58(f)(2))

Another means of validating the AO's accreditation processes is to review the AO's survey procedures. Addressed in the opening paragraph existing § 424.58(d)(2), this can involve CMS or its designated survey team—

- Performing a survey of an accredited DMEPOS supplier;
- Examining the results of the AO's survey of a supplier; and
- Observing an AO's survey of a supplier onsite.

After the review, CMS identifies whether (as stated in current § 424.58(d)(2)(i) through (iii)), the review indicates the following:

- At least a 10 percent disparity between the AO's and CMS' respective survey findings for non-immediate jeopardy standards.
- Any disparity between the AO's and CMS' respective survey findings for standards constituting immediate jeopardy.
- Regardless of the disparity rate, there are widespread and systemic problems in the AO's processes such that accreditation by the AO no longer provides CMS with adequate assurance that suppliers meet or exceed Medicare requirements.

Additional provisions regarding CMS' performance of a supplier survey (as a means of ascertaining the AO's performance) are addressed in existing § 424.58(b)(2). Specifically, the latter states that CMS performs supplier surveys on a representative sample basis or in response to substantial allegations of non-compliance.

We propose several modifications to the foregoing provisions to both consolidate and streamline our requirements and to enhance our ability to perform the aforementioned reviews. First, we propose to incorporate all provisions regarding validation surveys within new § 424.58(f)(2) rather than continue to have them split (as they currently are) between § 424.58(b)(2) and (d). We believe this would facilitate clarity and consistency.

Second, we propose in new paragraph (f)(2)(i) that CMS may survey suppliers to validate the AO's survey process. Such surveys can be comprehensive or focus on certain standards or requirements. We note that paragraph (f)(2)(i) would not include the three survey situations in the opening paragraph of existing § 424.58(d)(2), the provisions in § 424.58(d)(2)(i) through (iii), or references to sample bases and substantial allegations of non-compliance in § 424.58(b)(2). We believe that paragraphs (b)(2) and (d)(2), as

currently written, could be erroneously read as restricting our flexibility to: (1) conduct supplier surveys; and (2) reach conclusions that indicate problems with the AO's accreditation program. To illustrate, consider the following interpretations:

- Under paragraph (b)(2), CMS can only perform supplier surveys on a representative sample basis or in response to substantial allegations of non-compliance.
- Under the opening paragraph of § 424.58(d), the only types of permissible CMS supplier surveys are those mentioned in that paragraph.
- Under paragraphs (d)(2)(i) through (iii), any disparity rate of less than 10 percent or any detected problems that are not widespread or systemic prohibits CMS from taking any action against the AO based on the surveys.

Although we have never interpreted these paragraphs so narrowly, we wish to avoid any confusion on the matter and therefore will not include them in proposed paragraph (f)(2)(i). Instead, the latter would be broader and, in the process: (1) give CMS greater discretion regarding the types of supplier surveys that can be performed; and (2) allow CMS to conclude that the AO's accreditation program has deficiencies even if a minimum 10 percent disparity is not reached or the problems the surveys found are neither widespread nor systemic. In our view, any disparity percentage or detected problem is concerning because it could have led to a non-compliant supplier obtaining or retaining accreditation, potentially resulting in improper payments or beneficiary harm.

Third, existing § 424.58(b)(3) through (6) state, respectively, that—

- If CMS discovers that the supplier is non-adherent to the quality standards, CMS may revoke the supplier's billing number or require the AO to perform a subsequent full survey at the AO's expense;
- A supplier selected for a validation survey must authorize: (1) the survey to occur; and (2) the CMS survey team to monitor the correction of any deficiencies found during the survey;
- If the selected supplier does not comply with the existing authorization requirements of paragraph (b)(4), it does not meet the quality standards and may have its supplier billing number revoked; and
- If the survey finds that the supplier is non-compliant with one or more quality standards, the supplier no longer meets the quality standards and may have its supplier billing number revoked.

Except for changing “supplier billing number” to “enrollment” (the latter being the more accurate term), we do not propose revisions to these requirements, which we would respectively designate as new § 424.58(f)(2)(ii), (iii), (iv), and (v).

c. Deficiencies (§ 424.58(f)(3))

As part of the proposed statement under new § 424.58(c)(1)(xxiii), new paragraph (H) thereof would require the AO to agree to accept and adhere to any CMS-established deficiency definition as well as levels and categories of deficiencies. The aim of this is to enhance consistency among the AOs in how they determine whether a deficiency exists. To reiterate CMS' discretion in both this regard as well with respect to CMS' authority to establish quality standards under section 1834(a)(20) of the Act, we propose in new § 424.58(f)(3)(i) that CMS may define the term “deficiency”, establish levels and categories of deficiencies, and revise the quality standards. New § 424.58(f)(3)(ii) would require the AO in its accreditation activities to apply and adhere to: (1) any CMS-established definition of deficiency and categories and levels thereof; and (2) all CMS-established quality standards.

d. Additional Reviews (§ 424.58(f)(4))

We propose in new § 424.58(f)(4)(i)(A) to expand upon the reviews addressed in new § 424.58(f)(1) and (2) and permit CMS—at any time and for any reason—to conduct a review of the AO's processes or performance to—

- Validate the AO's representations to CMS (for example, its statements in new paragraph (c)(1)(xxiii)); or
- Assess the AO's adherence to its own policies and procedures, the provisions of § 424.58, and all other CMS requirements.

We also propose in new § 424.58(f)(4)(i)(B) that the scope, length, and timing of the review would lie within CMS' discretion. Furthermore, evidence of the AO's potential non-compliance with any of the policies and requirements addressed in new § 424.58(f)(4)(i)(A) is not required for CMS to perform a review.

In new § 424.58(f)(4)(ii)(A) through (H), we propose to list some of the types of reviews that CMS may perform either collectively or individually. Paragraphs (f)(4)(ii)(A) and (B) would respectively reference the reviews in new § 424.58(f)(1) and (2). Paragraphs (f)(4)(ii)(C) and (D) would reflect two of the previously mentioned reviews in existing § 424.58(d)(2): examining the results of an AO's surveys of suppliers

and observing onsite an AO's survey of a supplier. Proposed new paragraphs (f)(4)(ii)(E) through (H) would address the following reviews of the AO's onsite operations, similar to those for certified providers and suppliers in 42 CFR 488.8(h):

- Conducting onsite inspections of the AO's operations and offices.
- Requesting and reviewing documents.
- Interviewing AO personnel.
- Observing AO internal meetings concerning the accreditation process.

These proposals in new § 424.58(f)(4) are needed to give us greater flexibility and more means with which to assess the AO's performance. Indeed, current § 424.58 only references equivalency reviews, supplier surveys, and the AO's periodic submission of data as vehicles via which we can perform this task. We must be able to tailor the format, timing, and scope of our reviews to address particular circumstances. For instance, if we have reason to believe that an AO's surveys are being performed by unqualified personnel, we may seek to interview the surveyors to assess their knowledge and credentials. Even if we have not received any indication of non-compliance, we believe it is prudent to perform periodic AO reviews (that is, outside of the AO initial application and reapproval application processes) to confirm continued compliance—for such analyses may, in fact, reveal AO non-adherence to § 424.58. In short, only through a wide range of regular reviews can we be assured that the AO is conducting its accreditation activities consistent with all requirements.

6. Terminations of CMS-Approved AO Accreditation Programs (New § 424.58(g) and (h))

a. Voluntary Terminations

Sections 488.5(c)(2), 488.8(g)(2), and 488.1045(a) outline procedures via which an AO can voluntarily terminate its existing CMS-approved certified provider/supplier or HIT supplier accreditation program (respectively). To ensure that DMEPOS AOs seeking to voluntarily termination follow a specific, uniform process for doing so and, more importantly, that CMS is given adequate notice thereof, we propose to establish similar procedures in new § 424.58(g).

In paragraph (g)(1), we propose that an AO may voluntarily terminate its CMS-approved DMEPOS accreditation program at any time. In doing so, the AO per paragraphs (g)(1)(i) and (ii), respectively, must—

- Inform CMS of its decision no less than 120 calendar days before the termination effective date; and

- Provide written notice at least 90 days before the termination effective date to each of its accredited suppliers but not before notifying CMS of its decision under the previous bullet. The notice to each supplier must—

- ++ Describe the provisions in proposed new paragraph (g)(2) (discussed shortly) concerning the expiration dates of the supplier's accreditation with the terminating AO; and

- ++ Inform the supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminating AO expires and the effective date of its accreditation with a different AO) will result in the revocation of its enrollment under § 424.535.

We believe these requirements would give CMS and impacted suppliers sufficient notice of the AO's intentions and the implications of the AO's withdrawal. We consider the notification regarding lapses in accreditation particularly important, for the supplier must ensure it always remains accredited.

In new paragraph (g)(2), we propose that unless the supplier is otherwise determined to be non-adherent to the quality standards or other accreditation requirements, the supplier's accreditation with the terminating AO remains effective until the earliest of: (1) the expiration of its current term of accreditation with the terminating AO; and (2) the effective date of its accreditation with a different CMS-approved AO. We do not believe a supplier's accreditation should be correspondingly and automatically terminated when an AO voluntarily terminates its DMEPOS accreditation program. The AO's decision, in our view, is separate and distinct from the question of whether the supplier still complies with the quality standards and all other accreditation requirements. So long as the supplier remains compliant therewith, its accreditation should typically remain intact until one of the two aforementioned contingencies occurs.

b. Involuntary Terminations

(1) Reasons

Current § 424.58(d)(4)(i) and (ii) list two reasons for which CMS can terminate its approval of an AO's DMEPOS accreditation program:

- Accreditation by the AO no longer adequately ensures that its suppliers comply with the quality standards, and that failure to meet these requirements could (i) jeopardize the health or safety of Medicare beneficiaries and (ii)

constitute a significant hazard to public health; or

- The AO has not met its obligations regarding initial application or reapproval application procedures.

We believe these termination reasons may be too limited. For example, existing § 424.58(d)(4)(i) can only apply if the failure could jeopardize beneficiaries or public health. We do not believe the latter should be a prerequisite for termination. If the program does not ensure that suppliers meet the quality standards—which is the principal reason for the DMEPOS accreditation program in the first place—that alone is of great concern because it could result in improper payments. Put otherwise, the issue is not only beneficiary safety (critical though that matter is) but also protection of the Trust Funds. With respect to § 424.58(d)(4)(ii), the AO's obligations are not restricted to those involving the initial and reapproval application processes. They instead are constant throughout the entirety of the AO's period of CMS approval and require the AO's ongoing compliance with § 424.58. We believe our involuntary termination reasons should be much broader so as to address the previous situations and to ensure we have the ability to safeguard the Medicare program.

We thus propose the following provisions in new § 424.58(h).

In new paragraphs (h)(1)(i)(A) through (D), respectively, we propose that we may terminate our approval of an AO's accreditation program if CMS determines that—

- The AO no longer demonstrates reasonable assurance (as defined in paragraph (b));
- The continued approval of the AO's accreditation program poses an immediate jeopardy to the patients of the entities accredited under that program or otherwise constitutes a hazard to the public health;
- The AO is non-adherent to any provision of § 424.58. This includes, but is not limited to, situations where the AO has failed to comply with—

- ++ A term or condition of a statement or agreement in § 424.58(c)(1)(xxiii); or
- ++ A policy, procedure, or practice it outlined under paragraph § 424.58(c) as part of its initial or reapproval application or CMS-approved change thereto under § 424.58(e)(2) or (e)(7); or

- A pattern or practice exists of the AO's accredited suppliers being revoked under § 424.535(a) for failing to adhere to the quality standards.

We previously stated that as part of its initial or reapproval application, the AO must submit the information described

in paragraph (c)(1) to provide reasonable assurance. With reasonable assurance a crucial element of CMS' assessment of the AO's credentials and operations, we believe the failure to maintain it justifies termination under paragraph (h)(1)(i)(A). Paragraph (h)(1)(i)(B), meanwhile, mirrors the language in § 488.8(d) and existing § 424.58(d)(4)(i) regarding immediate jeopardy.

We recognize the broad nature of proposed paragraph (h)(1)(i)(C). Yet as already noted, AOs must at all times adhere to § 424.58, the terms of its statement in § 424.58(c)(1)(xxiii), and its current policies, procedures, and practices. Any failure to do so could lead to not only improper payments but also unsafe or low-quality services being provided by non-compliant suppliers. In light of our obligation to prevent this, we believe we must have the discretion to terminate the AO's approval in such instances. This does not mean CMS will automatically do so, especially in instances of very minor non-compliance. As discussed in the following sections of this proposed rule, there are other actions we might take in such cases. Nevertheless, given the wide variety of non-compliance situations that could arise, we believe termination should at least be an option.

As for proposed paragraph (h)(1)(i)(D), § 424.535(a) outlines several reasons for which we can revoke a provider's or supplier's (including a DMEPOS supplier's) enrollment based on a pattern or practice of conduct. These include, for example, a pattern or practice of: (1) submitting claims that fail to meet Medicare requirements; and (2) prescribing Part B or D drugs that is abusive or represents a threat to the health and safety of the Medicare program. The "pattern or practice" concept is intended to address situations where a sequence of provider or supplier actions indicates a potentially systemic problem. We believe this principle should apply to the AO's oversight of DMEPOS suppliers. If we find that a number of an AO's currently accredited suppliers fail to meet the quality standards, this could signify that the AO is not effectively ensuring its suppliers' compliance with the quality standards, perhaps due to insufficiently thorough surveys. Our proposed termination basis could help spur AOs to very closely examine its suppliers for compliance during the latter's initial accreditations and reaccreditations. We note, though, that we neither define "pattern or practice" in § 424.535(a) nor propose to do so in § 424.58. This is because we must be able to address each case based on its unique facts and circumstances.

We also propose under new § 424.58(h)(1)(ii) that CMS could terminate its approval of the AO's accreditation program effective on the date of the termination notification letter to the AO (described in proposed new paragraph (h)(2)) or any date thereafter. Considering, as already stated, the risks to the Trust Funds and Medicare beneficiaries that AO non-compliance could lead to (such as continued substandard services offered by non-compliant suppliers), we believe that having to wait 30 days, 60 days, or longer before the termination is effective could result in considerable improper payments and possible patient harm. While we are including an "or any date thereafter" caveat to § 424.58(h)(1)(ii) to account for situations where a slightly later date might be warranted, we believe these will be rare.

(2) Processes

We propose in new § 424.58(h)(2) through (5) to outline operational procedures for terminating an AO's approval and to address the consequent impact on suppliers. Doing so would help the AOs, suppliers, and other stakeholders understand what to expect when a termination occurs. To promote uniformity with existing processes, and with some exceptions, §§ 424.58(h)(2) through (4) would be akin to various provisions in §§ 488.1030(f), 488.8(e), and 488.1045(b).

Under proposed § 424.58(h)(2), CMS would give written notice to the AO of its termination decision. The notice must include the reason for and effective date of the termination. Under § 424.58(h)(3), and as with AO initial application submissions, CMS would announce its decision (and the effective date thereof) on its website. This would help ensure the public is made aware of the termination as soon as possible.

In § 424.58(h)(4), and so affected suppliers receive individualized notice beyond the CMS website announcement, the terminated AO would have to give written notice of the termination and its implications to each of its accredited suppliers within 30 calendar days after the CMS website announcement. The notice to each supplier would have to—

- Explain the provisions in § 424.58(h)(6) concerning the expiration dates of the supplier's accreditation with the terminated AO; and
- Inform the supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminated AO expires and the effective date of its accreditation with a different AO) results in its enrollment being revoked under § 424.535.

We also propose the following in new § 424.58(h)(5) and (6)(i)(A) through (C), respectively:

- The terminated AO would have to work collaboratively with CMS to direct its accredited suppliers to the remaining CMS-approved AOs within a reasonable period of time.
- Unless the supplier is otherwise determined to be non-adherent to the quality standards or other accreditation requirement, the supplier's accreditation with the terminated AO remains effective until the earliest of—
 - ++ The expiration of its current term of accreditation with the terminated AO;
 - ++ The effective date of its accreditation with a different CMS-approved AO; or
 - ++ A date specified by CMS based on the circumstances of the termination of the AO's approval.

We believe new paragraphs (h)(4), (5), and (6)(i) would ease suppliers' transition to a new AO by: (1) explaining the implications of the termination; (2) facilitating CMS-AO collaboration; and (3) emphasizing that—as with proposed §§ 424.58(g)(2) regarding voluntary terminations—the supplier's accreditation does not automatically end with the AO's departure. By the same token, paragraph (h)(4) and the required letter would stress to the supplier that there can be no gaps in its accreditation. This may require the supplier to promptly seek accreditation with another AO before its current accreditation expires.

We note two additional matters regarding proposed § 424.58(h)(6)(i). First, the opening language thereof that states "unless the supplier is otherwise determined" merely reiterates that the supplier's accreditation status remains intact only if it is still in compliance with the quality standards and all other accreditation requirements. Second, and with respect to paragraph (h)(6)(i)(C), there could be isolated instances where CMS may assign to a supplier an accreditation termination date that is earlier than the dates in proposed paragraphs (h)(6)(i)(A) and (B). This would most commonly occur when we have concerns that the terminated AO may not have surveyed or assessed certain suppliers with the requisite thoroughness and efficiency, which raises significant questions as to whether the supplier was compliant with the quality standards. Should CMS specify such a date, CMS would under new paragraph (h)(6)(ii) notify the affected supplier in writing thereof and identify the deadline by which the supplier must be reaccredited by a different AO. CMS would ensure that the deadline is far enough in advance to

give the supplier time to be reaccredited.

In addition, we propose in new § 424.58(h)(7) that the terminated AO must refund to a supplier all payments the latter made to the AO in accordance with the supplier's request for accreditation or reaccreditation but before the AO notified the supplier of its final determination regarding the supplier's request. We do not believe an AO whose approval has been terminated should be able to keep the monies the supplier paid it when the requested service—accreditation or reaccreditation—was not fully rendered (that is, the final decision was not made). Fundamental fairness to the supplier requires, in our review, the refund of such payments.

7. AO Suspensions and Probations (New § 424.58(i) and (j))

Termination is presently the only remedy available to CMS under § 424.58 to address AO performance issues. Although we proposed in § 424.58(h)(1) to expand the grounds for which termination can apply, we recognize the seriousness of a termination and would generally only take this step in exceptional circumstances. Yet under current § 424.58, this could leave the non-compliance unresolved because of our lack of other, perhaps more suitable remedies. In other words, we do not believe AO non-compliance should only be addressable by an all-or-nothing, termination-or-no termination approach. Having multiple available remedies would allow us to correspond our action to the relative severity of each case.

a. Suspension

We propose in new § 424.58(i) to have the ability to suspend an AO's accreditation program. Under paragraph (1)(i), suspension could occur if we determine that the AO no longer demonstrates reasonable assurance (as defined in paragraph (b)) or is non-compliant with any provision of § 424.58. The non-compliance can include, but is not limited to, situations where the AO has failed to—

- Comply with a term or condition of a statement or agreement in § 424.58(c)(1)(xxiii); or
- Adhere to a policy, procedure, or practice it outlined under § 424.58(c) as part of its initial or reapproval application or a CMS-approved change thereto under § 424.58(e)(2) or (e)(7).

We also propose that CMS may suspend the AO's accreditation program if there is a pattern or practice of the AO's accredited suppliers being revoked under § 424.535 for failing to comply with the quality standards.

These grounds are also applicable to terminations but are sufficiently broad to enable us to apply a lesser sanction if the circumstances warrant. (For example, the § 424.58 non-compliance may not be significant enough to, in our view, justify a termination).

New § 424.58(i)(2) would outline a suspension's components. Paragraph (i)(2)(i) would state that except as otherwise specified or permitted by CMS, the AO could not conduct any DMEPOS accreditation activities while suspended. We believe the opening caveat is necessary should we need the AO, despite its suspension, to perform certain functions, such as completing an ongoing survey. Paragraph (i)(2)(ii), meanwhile, would state that—

- CMS determines the length of the suspension, which would be a maximum of 1 year; and
- Upon the expiration of the suspension period, CMS either lifts the suspension or terminates the AO's approval.

Aside from the maximum 1-year period, we do not believe a fixed suspension length should be established in regulation. Since every situation will differ, we must have the discretion to tailor the suspension length to the specific facts of the case; to illustrate, the non-compliance at issue may be substantial enough to warrant a suspension but only for a fairly brief period because the non-compliance can be resolved expeditiously. We believe a 1-year maximum is appropriate because if the AO cannot rectify the non-compliance within such an extensive timeframe, this indicates systemic issues that can warrant termination.

For the same reasons behind proposed paragraph (h)(2) regarding terminations, we propose in new paragraph (i)(2)(iii) that CMS may suspend the AO's program effective the date of the suspension notification letter described in paragraph (i)(3) or any date thereafter.

We propose in new paragraph (i)(3) that CMS sends written notice of the suspension decision to the AO. The notice would include the reason(s) for, the effective date of, the length of, and the terms of the suspension (for instance, application of a CAP; whether the AO may perform certain functions during the suspension; etc.), as well as the steps the AO must take to have the suspension lifted. To confirm that the AO received the notice, we propose in new paragraph (i)(3)(ii) that the AO must notify CMS of this in writing within 3 calendar days of receipt.

In new paragraph (i)(3)(iii), we propose that no later than 3 calendar days after our receipt of the acknowledgement in paragraph (i)(3)(ii),

CMS would post on its website a notice of the suspension. We do not believe publication in the **Federal Register** would be practical since, in some cases, the suspension may conclude before **Federal Register** publication. Moreover, publication on our website would allow us to rapidly notify stakeholders of the suspension well before it expires.

Paragraph (i)(4) would address the status of the suspended AO's accredited suppliers. Akin to supplier statuses with AO voluntary and involuntary terminations, we propose in new paragraphs (i)(4)(i)(A) through (C), respectively, that if the AO's accreditation program is suspended, the accreditation status of its suppliers remains effective through the length of the suspension unless—

- The supplier's current term of accreditation with the suspended AO expires during the suspension;
- The supplier is otherwise determined to be non-adherent to the quality standards or other accreditation requirement; or
- CMS specifies a different accreditation termination date based on the circumstances of the suspension of the AO's accreditation program.

New paragraph (i)(4)(ii)(A) would state that if paragraph (i)(4)(i)(A) applies, the supplier must be recredited by: (1) its AO if the latter's suspension has been lifted; or (2) a different CMS-approved AO. New paragraph (i)(4)(ii)(B) would state that if paragraph (i)(4)(i)(C) applies, CMS notifies the affected supplier in writing of the deadline by which the supplier must be recredited. Meanwhile, new paragraph (i)(4)(iii) would reiterate that any lapse in the supplier's accreditation results in the supplier's revocation of enrollment. Both (i)(4)(ii) and (iii) are intended to help ensure there are no gaps in the supplier's accreditation status under § 424.58.

New paragraph (i)(5) would address the circumstances under which a suspension is lifted and the processes associated therewith. In paragraphs (i)(5)(i)(A) through (C), respectively, we propose that CMS would lift a suspension if all of the following are met:

- The reasons for it no longer exist.
- The AO demonstrates reasonable assurance (as defined in paragraph (b)).
- The AO is in compliance with all provisions of § 424.58.

We believe that even if the specific issue that led to the suspension has been corrected, it is possible that other instances of non-compliance exist, hence the need for paragraphs (i)(5)(i)(B) and (C).

In paragraph (i)(5)(ii), and for the same reasons behind proposed paragraphs (i)(3)(i) through (iii), we propose that if the suspension is lifted, CMS would—

- Send the AO written notice that the suspension has been lifted;
- Require the AO to notify CMS in writing of its receipt of the notice within 3 calendar days of such receipt; and
- No later than 3 calendar days after receipt of the AO's acknowledgement, publish on its website a notice of the lifting of the AO's suspension and the reasons for it.

We propose in new paragraph (i)(6) to duplicate proposed paragraph (h)(7) regarding refunds. Irrespective of whether a termination or a suspension is involved, our concern remains the same: the potential for the AO to retain payments for a service it did not fully furnish. We do not believe the supplier should, in effect, be financially penalized for the AO's non-compliance that led to the termination or suspension. We note that the suspension would not be lifted before all required refunds to suppliers under paragraph (i)(6) have been paid.

In new paragraph (i)(7), we propose that nothing in paragraph (i) would prohibit CMS from suspending an AO's accreditation program more than once. This would help preserve our flexibility to take the most appropriate action to address AO non-compliance; for example, a second suspension may be more appropriate than a suspension followed by a termination several years later.

b. Probation

To further enhance our ability to address AO non-compliance in a manner proportional to the degree thereof, we propose to establish a process in new § 424.58(j) for placing an AO's accreditation program on probation in lieu of a termination or suspension. We note that Part 488 contains a probation process for AOs that accredit certified providers, certified suppliers, and HIT suppliers. However, our provisions in new § 424.58(j) would differ somewhat from those (for example, concerning the maximum length of the probationary period) given the different characteristics of the DMEPOS accreditation program and our need to have the latitude to address AO non-compliance in the most appropriate manner.

In paragraph (j)(1), we propose to have the discretion to place an AO's accreditation program on probation and require its successful completion of a CAP in the following instances—

- CMS determines that the DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

- CMS determines that the AO is non-compliant with any provision of § 424.58. This could include the aforementioned terms, conditions, procedures, etc., described in proposed new paragraphs (h)(1)(i)(C) and (i)(1)(ii).

- CMS determines that there is a pattern or practice of the AO's accredited suppliers being revoked under § 424.535 for not complying with the quality standards.

- The suspension period for the AO under paragraph (i) has expired and CMS determines that a subsequent probationary period and associated CAP are warranted.

In paragraph (j)(2)(i), we propose that CMS would give the AO written notice of its decision to place it on probation. To ensure that the AO understands the basis for and the particulars of the probation, the notice would include—

- The reason(s) for CMS' decision;
- The length of the probationary period, which would not exceed 1 year;
- The CAP's terms;
- The requirements and deadline for achieving compliance; and
- An explanation of how CMS would monitor the AO's efforts to resume adherence under the CAP (for example, performing reviews under paragraph (f)).

We propose in new paragraph (j)(2)(ii) that except as otherwise prescribed in the CAP, the AO could continue its accreditation activities as normal.

In new paragraph (j)(3)(i), we propose that when the probationary period concludes, CMS would notify the AO in writing of—

- Whether the AO is in compliance with all requirements of § 424.58;
- The reason for the determination in the previous bullet; and
- The consequences of the determination (for example, termination or suspension of accreditation, successful completion of and cessation of the probationary period and CAP).

In paragraph (j)(3)(ii), we propose that we may send this notice, terminate the probationary period, and end the CAP prior to the end of designated probationary period if we determine that the AO is again compliant, for this would eliminate the continued need for the probation and CAP.

Several aspects of new paragraph (j) must be addressed. First, the probationary period and the CAP would be intertwined, meaning the latter would be the core element of the former. Second, CMS, rather than the AO, would establish the terms of the CAP.

We believe this would better ensure that the issues resulting in the probation will be addressed. Third, there could be instances where although a suspension has been lifted, we need to closely monitor the AO's resumption of activities via probation and a CAP. We believe this would be a prudent step in ensuring that the prior problems do not resurface and that new ones do not arise. Fourth, CMS would retain the discretion to limit or not limit the AO's accreditation activities during the probationary period. This would help us balance the type and degree of AO non-compliance with the need to avoid unduly disrupting the AO's ongoing DMEPOS program activities. Finally, we are not proposing to post notice of the probation and CAP on the CMS website, for the AO under these actions would typically be able to continue their activities without interruption.

8. CMS Discretion, Change in Non-Compliance Actions (New § 424.58(k))

We have stressed the importance of CMS having several types of administrative actions to address AO non-compliance. To confirm CMS' discretion to determine which action should be imposed and, if circumstances warrant, to escalate a currently imposed action to a more significant one, we propose the following in new § 424.58(k). First, under paragraph (k)(1), CMS could impose an action in § 424.58(h), (i), or (j) in lieu of another such action in paragraph (h), (i), or (j) if the same ground(s) for either exists. For example, if the AO is non-compliant with the requirements at § 424.58, CMS could terminate the AO's approval rather than suspend the accreditation program or place it on probation. Second, § 424.58(k)(2) would state that CMS could terminate—

- An AO's probation (either before or in accordance with the probationary period's original expiration date) and impose a suspension or termination if a ground for either of the latter actions exists; or
- An AO's suspension (either before or in accordance with the suspension's original expiration date) and impose a termination if a basis for termination exists.

The main reason for § 424.58(k)(2) is that we do not wish to be tied to a particular action for an extended period if, for instance, additional problems with the AO arise that warrant a more substantial action. To illustrate, assume we placed an AO on probation with an initially assigned period of 3 months. If an immediate jeopardy situation arises a month into the probation, we must have

the ability to immediately terminate the AO without having to wait until the 3-month probationary period expires.

9. Reconsiderations and Rebuttals (New § 424.58(l))

a. Denials and Involuntary Terminations

Current § 424.58(e)(1) outlines the reasons for which an AO may file a written request for reconsideration of a CMS determination that the AO does not provide reasonable assurance that the suppliers it has accredited meet the quality standards. The procedures of the reconsideration process are outlined in § 424.58(e)(2) through (9). We propose to remove all these reconsideration provisions from § 424.58 and, in new § 424.58(l) instead utilize the reconsideration processes in 42 CFR part 498 for denied and involuntarily terminated AOs. There are two reasons for this. First, the part 498 procedures are currently available for providers and suppliers whose enrollments are denied or revoked under § 424.530 or § 424.535, respectively. We view the denial of an AO's application for approval and the involuntary termination of said approval as akin to these two situations. Second, Part 498, unlike existing § 424.58(e), contains procedures for appeals beyond the initial reconsideration level, such as to the Administrative Law Judge (ALJ) and the Department Appeals Board (DAB). We believe these appeal rights should be available to denied or involuntarily terminated AOs to the same extent as with denied or revoked providers and suppliers.

Section 498.3(b) lists situations in which CMS makes an initial determination. We propose to add new paragraphs (b)(21) and (22) to § 498.3. The former would include denials under paragraph (c)(4) or (d)(4). The latter would include involuntary terminations under paragraph (h)(1). We would also state in new § 424.58(l)(1) that the AO could request a reconsideration under part 498 of any of these three initial determinations.

b. Suspensions and Probationary Periods

With respect to suspensions and probationary periods, neither of these would involve the elimination of the AO's DMEPOS accreditation program approval altogether (as would a termination) but, in many cases, merely the temporary cessation of or potential restrictions on the AO's activities. Both involve interim measures rather than permanent action on our part. Considering also that the suspension or probationary period may be brief

(especially with probationary periods), the period in question may have expired before the end of the AO's timeframe for requesting a reconsideration under 42 CFR part 498.

For these reasons, we believe a rebuttal process—similar to that in § 424.546—would be more appropriate than a reconsideration process for AOs whose accreditation programs have been suspended or placed on probation. It is shorter and more expedited—consistent with the potentially shorter suspension and probationary periods—than the reconsideration process. Yet it still affords the affected AO an opportunity to be heard. It has long been used for certain interim CMS actions that do not involve the party's permanent removal from engaging in certain Medicare activities. These interim actions include, but are not limited to—

- A deactivation under § 424.540, which involves a stoppage (but not a termination) of a provider's or supplier's Medicare billing privileges.
- A Medicare payment suspension (or offset or recoupment of Medicare payments) under § 405.372 or § 405.373, respectively.

We propose in new paragraph (l)(2) to outline the procedures via which an AO may rebut a CMS determination to suspend or place on probation its DMEPOS accreditation program. As previously noted, these procedures duplicate the existing rebuttal process in § 424.546 for a deactivation of Medicare billing privileges.

In new paragraph (l)(2)(i)(A), we propose that if an AO receives notice from CMS that its DMEPOS accreditation program has been suspended or placed on probation, the AO has 15 calendar days from the date of such notice to submit a rebuttal to CMS. We believe that a 15-day period, which is currently used for deactivation rebuttals, effectively balances the needs to: (1) promptly take measures to safeguard DMEPOS program integrity; and (2) ensure that the AO has time to submit a rebuttal.

In new paragraph (l)(2)(i)(B), we propose that CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (l)(2)(i)(A). This would enable CMS to account for special circumstances that may justify a longer period (for example, circumstances beyond the AO's control would prevent it from submitting a timely rebuttal).

In new paragraph (l)(2)(ii)(A) through (D), we propose that any rebuttal must—

- Be in writing;
- Identify the facts or issues about which the AO disagrees with CMS'

determination, including the reasons for disagreement;

- Include all documentation the AO wants CMS to consider in its review of its determination; and
- Be submitted in the form of a letter that is signed and dated by the AO's CEO (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) or a legal representative (as defined in 42 CFR 498.10). We would also include the provisions from § 424.546(b)(4) regarding legal representatives (for example, a required statement that the representative has the authority to represent the AO).

We believe the provisions in paragraph (l)(2)(ii) are necessary to ensure: (1) a uniform and standard process for submitting AO rebuttals; (2) that there is written documentation of the AO's contentions; (3) that CMS has sufficient information to perform its review; and (4) that the AO authorized the rebuttal submission.

In paragraph (l)(2)(iii), we propose that the AO's failure to submit a timely and compliant rebuttal would constitute a waiver of all rebuttal rights under paragraph (l)(2). This provision would not only specify the consequences of an untimely or non-compliant rebuttal but also help encourage the AO to abide by paragraphs (l)(2)(i) and (ii) should it choose to rebut a suspension or probation.

In paragraph (l)(2)(iv), we propose that upon receipt of a timely and compliant AO rebuttal, CMS reviews it to determine whether the imposition of the suspension or probation was correct. We believe this provision would adequately notify AOs of the scope of CMS' review.

In paragraph (l)(2)(v), we propose that CMS would not be required to delay the imposition of the suspension or probation pending the completion of CMS' review of the rebuttal. This provision is needed so CMS can expeditiously enforce the program integrity protections associated with the suspension or probation while recognizing the AO's ability to challenge the suspension or probation via the rebuttal process. If CMS determines that the suspension or probation was erroneous, it would be reversed.

In new paragraph (l)(2)(vi), we propose that a CMS determination made under paragraph (l)(2) would not be an initial determination under § 498.3(b) and therefore, would not be appealable. This would clarify for AOs that a rebuttal is the only administrative remedy available for suspension or probation.

10. Consulting (New § 424.58(m))

As previously mentioned, CMS issued a February 15, 2024, proposed rule addressing several topics regarding certified provider/supplier accreditation. One such subject was consulting services provided by AOs, their consulting divisions, or separate business entities to Medicare-participating health care facilities. One example of consulting services the proposed rule cited involves an AO's review of facility standards and promised early intervention and action through simulation of a real survey, such as a mock survey with comprehensive written reports of findings. This situation is of particular concern to us. The purpose of the DMEPOS accreditation survey is to objectively assess the supplier's compliance with the DMEPOS quality standards without the AO's prior aid in helping the supplier achieve such compliance. That is, the supplier should be able to adhere to the quality standards on its own merits. We believe it would be a conflict of interest if the AO had effectively "coached" the supplier on how to pass the survey that the AO later performed. In addition, the AO might be reluctant to find non-compliance on the survey—even though such non-compliance exists—because this could reflect poorly on the AO's pre-survey assistance. Either situation could lead to an unqualified DMEPOS supplier becoming accredited and enrolled. For this reason, we believe that certain protections against this activity are warranted and thus propose the following provisions.

In new § 424.58(m)(1), we propose to define the terms "consulting" and "consulting services" for purposes of proposed paragraph (m). The terms would mean those services furnished by a DMEPOS AO (or by its consulting division or separate business entity (such as a company or corporation) that furnishes such services) for the review of a DMEPOS supplier's standards, processes, policies, and functions for compliance with the AO's standards, the DMEPOS quality standards, or other Medicare requirements through simulation of a real survey, such as a mock survey, with comprehensive written reports of findings and early intervention and action to correct deficiencies prior to an actual accreditation survey.

We note two things about this proposed definition. First, it encompasses the previously referenced situation regarding prior assistance and mock surveys. It also includes language from the February 15, 2024, proposed

rule, concerning the various organizational components of the AO to which the consulting prohibition would apply, such as the AO's consulting divisions. This would help foster consistency with that proposed rule. Second, the definition would not be restricted to consulting that is fee-based. We recognize that the February 15, 2024, proposed rule focused on paid consulting services. Yet we believe the critical factor is the provision of the DMEPOS AO consulting service itself rather than whether payment was made. In other words, the assistance furnished in helping the supplier prepare for and pass the survey—instead of the monetary compensation—is what triggers the risks of a conflict of interest and subsequent potential for an otherwise unqualified supplier to become accredited.

In new paragraphs (m)(2)(i) through (iii), we propose that, except as provided in proposed § 424.58(m)(3), an AO or its consulting division or separate business entity (such as a company or corporation that provides consulting) may not provide consulting services in the following instances:

- To any new supplier before the completion of the initial accreditation survey, meaning the first survey of a supplier that has not previously received accreditation services from that AO. If a supplier is later voluntarily or involuntarily terminated from that AO's services and thereafter retains the services of that same AO or a new one, the first survey of that supplier by the same or new AO would be considered an initial accreditation survey.
- To a supplier the AO accredits within 6 months prior to the supplier's next scheduled re-accreditation survey. A re-accreditation survey would be any subsequent accreditation survey the AO performs after the initial survey.
- To a supplier to which the AO furnishes accreditation services, in response to a complaint the AO receives concerning that supplier.

These three prohibitions are similar to those included in the February 15, 2024, proposed rule and, in our view, would help address our previously referenced concerns regarding consulting services.

In paragraphs (m)(3)(i) through (iv), respectively, we propose the following four situations—which the February 15, 2024, proposed rule also addressed—where an AO, its consulting division, or separate business entity may provide consulting services to the suppliers it accredits.

The first is during the 6-month period after an initial or re-accreditation survey is performed. In the immediate months following the survey, we believe the risk

of consultative influence on the survey's objectivity is reduced.

The second is when CMS or its contractor receives and investigates complaints about an AO's accredited supplier where an immediate jeopardy deficiency or basis for revocation of enrollment under § 424.535 is identified. However, the consulting may occur only after the investigation is completed and can only address those issues identified in the investigation. The difference between this scenario and that in proposed paragraph (m)(2)(iii) is that CMS, rather than the AO, performs the review of possible non-compliance. Hence, the potential that the AO will conduct the review in a subjective manner is moot.

The third and fourth are as follows:

- Consulting services provided to suppliers that the AO does not accredit at the time the services are furnished.
- General education the AO furnishes about its accreditation program.

Neither of these situations invokes the concerns we previously addressed regarding coaching and subjectivity.

In paragraph (m)(4), we propose that the AO must furnish to CMS upon CMS' request and with each initial and reapproval application under paragraphs (c) and (d) of this section, a report containing the following information:

- Whether the AO or an associated consulting division or company the AO has established furnishes consulting services.
- The names, National Provider Identifiers, and addresses of all suppliers to which the AO or its associated consulting division or company has furnished consulting services during the prior 6-month timeframe.
- The dates such services were provided to each supplier.
- Whether the AO has ever furnished, or is currently furnishing, accreditation services to any supplier identified in the report.
- For each supplier listed in the report, the dates of: (1) its most recent accreditation survey; and (2) the next re-accreditation survey due to be performed.
- A description of the consulting services provided to each supplier in the aforementioned report.

This information, which mirrors that in the February 15, 2024, proposed rule, would help CMS ascertain whether the AO is compliant with the provisions of paragraph (m).

In paragraph (m)(5)(i), we propose that the DMEPOS AO, its consulting division, or separate business entity must have and comply with the

following written consulting policies and procedures. At a minimum, these policies and procedures, which are referenced in the February 15, 2024, proposed rule regarding certified providers and suppliers, must include the following:

- The AO's consulting services must be furnished by a separate division of the AO or separate business entity (such as a company or corporation) that is separate from the AO's accreditation division.
- The AO's consulting division or separate business entity must maintain separate staff from that of the AO's accreditation divisions to ensure that—
 - ++ The consulting division personnel do not conduct the AO's accreditation division functions; and
 - ++ The AO's accreditation division staff do not conduct consulting division functions.
- An AO's accreditation staff and surveyors are prohibited from marketing the AO's consulting services to the AO's accreditation clients.

We believe proposed paragraph (m)(5)(i) would help further prevent conflicts of interests regarding these services by requiring a separation of units and staffs that perform accreditation activities from those providing the consulting services.

To help verify the AO's compliance with paragraph (m), we also propose in new paragraph (m)(5)(ii) that an AO that provides consulting services must submit its written consulting firewall policies and procedures to CMS by a date specified by CMS and with each application for initial approval or reapproval.

11. Other Relationships Involving Potential Conflicts of Interest (New § 424.58(n))

a. AO/Supplier Relationships

The February 15, 2024, proposed rule not only addressed consulting services but also noted relationships between AO officials and the suppliers the AO accredits. The proposed rule expressed concerns, which we share with respect to DMEPOS AOs and suppliers, that such a relationship could unduly influence the AO's survey performance and results and, consequently, the AO's accreditation decision. To illustrate, we explained in that proposed rule that an AO owner, surveyor, or employee involved in a survey of a provider or supplier with whom said individual has a relationship or interest relationship could have compromised judgment (consciously or unconsciously) regarding that facility; such a surveyor

could be inclined to minimize or ignore deficiencies or possibly persuade the other survey team members to do so.⁶⁷ This is, in fact, what occurred in the previously mentioned March 2025 Southern District of Florida criminal case. Even in situations where the owner, surveyor, or employee with the interest or relationship is not part of the survey team, the individual could attempt to influence the team's decision by, for example, advocating on the supplier's behalf.⁶⁸

As already stated in this section VI.B. of this proposed rule, objectivity in the AO's survey and decision-making process is of the utmost importance. The relationships and interests described in the previous paragraph—and in our earlier discussion of proposed § 424.58(c)(1)(vii)(D)—can place this concept at risk, mostly by potentially enabling suppliers that are, in actuality, non-compliant with the quality standards to nonetheless pass the survey and obtain or retain accreditation. The result would be unqualified suppliers improperly receiving payments from Medicare and possibly harming beneficiaries. Like with our consulting

proposals, we believe that safeguards against this type of influence are needed. We therefore propose to include them in new paragraph (n)(1); with modifications, these provisions are similar to those included in the February 15, 2024, proposed rule.

In paragraph (n)(1)(i), we propose that if an AO owner, surveyor or employee (currently or within the previous 2 years) has or had an interest in or relationship (as described in proposed § 424.58(c)(1)(vii)(D)) with a DMEPOS supplier accredited by the AO, the AO owner, surveyor, or employee is not permitted to—

- Participate in the survey of that DMEPOS supplier;
- Have input into the results of the survey and accreditation for that DMEPOS supplier;
- Have involvement with the pre-or post-survey activities for that DMEPOS supplier; or
- Have contact with or access to the records for the survey and accreditation of that DMEPOS supplier.

We believe these prohibitions would help reduce the risk that an AO owner, surveyor, or employee will improperly influence the DMEPOS supplier's survey and accreditation.

We proposed in new § 424.58(c)(1)(vii)(D) to define

“immediate family member” to help explain some of the conflict-of-interest affiliations that fall within that paragraph. So as to tie this definition to proposed (n)(1), we propose in new paragraph (n)(1)(ii) that, for purposes of new paragraph (n)(1), the term “immediate family member” would have the same meaning as that in paragraph (b).

Per proposed § 424.58(c) and (d), the conflict-of-interest information described in § 424.58(c)(1)(vii)(D) must be furnished with the DMEPOS AO's initial and reapproval applications. Given this data's importance and the need to avoid conflicts-of-interest, however, we propose in new paragraph (n)(1)(iii) that CMS may request any and all of this information at any time outside of the initial approval and reapproval processes.

To help the public better understand the relationship between the current proposed rule and the February 15, 2024, proposed rule, we have prepared the following table. It identifies three sets of our proposed provisions that, to varying degrees, duplicate certain provisions in the February 15, 2024, proposed rule but contains several notable differences.

⁶⁷ 89 FR 12011.

⁶⁸ *Ibid.*

TABLE 36: COMPARISON BETWEEN PROPOSED AO RULES

Provision	Proposed AO DMEPOS Rule	February 15, 2024, Proposed Rule	Differences
Definition of unannounced survey	See proposed 424.58(b)	Same as proposed 424.58(b)	Only difference is change from “facility” to “DMEPOS supplier” in proposed 424.58(b) (which only applies to DMEPOS suppliers)
Consulting	Prohibit all consulting services by an AO and its associated consulting divisions or companies to any DMEPOS to which the AO provides accreditation services: (1) prior to an initial accreditation survey; and (2) within 6 months of the next scheduled re-accreditation survey.	Prohibit all fee-based consulting services by an AO and its associated consulting divisions or companies to any health care provider or supplier to which the AO provides accreditation services: (1) prior to an initial accreditation survey; and (2) within 12 months of the next scheduled re-accreditation survey.	DMEPOS timeframe is 6 months instead of 12 months due to the proposed annual reaccreditations. So as to not hinder otherwise legitimate consulting arrangements, DMEPOS restrictions limited to situations involving mock surveys performed by an AO. DMEPOS prohibitions would not be limited to “fee-based” consulting. It is the consulting service itself and the impact it could have on the survey’s integrity – rather than whether compensation is involved – that is our central concern.
Conflict-of-Interest (COI)	AO submission of COI policies with each initial and reapproval application and upon CMS request.	AO submission of COI policies with each initial and reapproval application.	More infrequent submissions would reduce burden.

b. NPE/AO Relationships

NPEs (of which there are two nationwide) process DMEPOS Form CMS-855S enrollment applications. This involves, for example, (1) verifying the data the supplier furnished on or with the application; (2) performing a site visit; and (3) ensuring the supplier meets all Medicare requirements. The latter includes confirming that the supplier is accredited per § 424.58.

None of our current DMEPOS AOs are NPEs or parents or subsidiaries thereof; that is, there are no organizational relationships or ties between existing DMEPOS AOs and NPEs. This is important for the same overriding reason behind proposed paragraph

(n)(1): the need for objectivity. Consider the following hypotheticals:

- *Scenario 1:* An NPE’s owner is a DMEPOS AO. The AO accredits 100 new DMEPOS suppliers within a given period, and the NPE enrolls them. Over the succeeding months, the NPE receives information from parties other than the AO that a significant number of these suppliers are, in fact, non-compliant with the quality standards and other enrollment requirements. Since its owner accredited these suppliers, the NPE may be reluctant to revoke their enrollments because it could reflect poorly on the owner and possibly jeopardize its status as a DMEPOS AO.

- *Scenario 2—*The NPE itself is an AO. After accrediting a particular

supplier, the entity—in its capacity as an NPE—detects problems with the supplier’s initial enrollment application or later finds that grounds exist for deactivating the supplier’s billing privileges under § 424.540. In either case—and wanting to maintain a good relationship with the supplier—the NPE may decline to deny the application or deactivate the supplier out of concern the supplier may utilize a different AO in the future. This could result in non-compliant suppliers receiving or continuing to receive many thousands of Medicare dollars.

However, our concerns are not limited to NPEs. We believe that any CMS contractor with any oversight responsibility of DMEPOS suppliers could also present conflict-of-interest

issues. These could include, but would not be limited to, Durable Medical Equipment Medicare Administrative Contractors (DME MACs), which process DMEPOS claims, and contractors that perform site visits of DMEPOS suppliers. To illustrate, suppose a DMEPOS site visit contractor (SVC) is also a DMEPOS AO. The entity performed a survey of, and accredited, DMEPOS Supplier X. In its role as an SVC, it conducted a site visit of X 3 months later. Although X did not appear meet the definition of “operational” in § 424.502, the entity might be reluctant to make this finding because it could cast doubts on the thoroughness of its AO survey 3 months earlier. This could result in the supplier becoming enrolled and receiving payments while non-operational.

To avoid such conflict-of-interest situations and to help facilitate the impartiality of DMEPOS AO accreditation decisions, we propose in new § 424.58(n)(2) that an entity may not serve as a CMS-approved DMEPOS AO if it is currently a CMS contractor—or an owner or subsidiary thereof (regardless of the ownership percentage involved).—with any oversight responsibility of DMEPOS suppliers. We also solicit comment on whether this prohibition should extend to situations where, similar to paragraph (n)(1), there are familial relationships between owners and employees of DMEPOS AOs and the CMS contractor—for instance, whether an organization should be prohibited from being a DMEPOS AO if it has owners or employees who are immediate family members of NPE owners or employees.

12. AO Changes of Ownership (New § 424.58(o))

Section 488.5(f) contains robust procedures for when an AO undergoes a change of ownership (as that term is defined in § 489.18(a)(1) through (3)). They address matters such as: (1) the notice and accompanying information and acknowledgments the AO must furnish to CMS; and (2) the impact on the AO’s accredited providers and suppliers. However, § 424.58 contains no process for AO ownership changes. We note that § 488.1030, which addresses HIT supplier accreditation, states in paragraph (g) that an AO seeking to undergo a change of ownership is subject to the requirements at § 488.5(f). We propose the same cross-referencing approach in new § 424.58(o), under which DMEPOS AO changes of ownership would be governed by § 488.5(f).

13. Requirement for Suppliers To Be Accredited (Revisions to § 424.57)

As already noted, § 424.57 primarily addresses conditions of payment and supplier standards that suppliers must meet to enroll in and bill Medicare. Yet it also addresses accreditation requirements for DMEPOS suppliers; specifically, § 424.57(c)(22) states that these suppliers and all of their locations must be accredited by a CMS-approved AO to receive and retain a supplier billing number. Given our proposed strengthening of the DMEPOS accreditation program requirements in § 424.58, we believe corresponding enhancements to § 424.57 are necessary. Whereas our § 424.58 proposals focus to a considerable degree on the AO’s execution of its DMEPOS program, our revisions to § 424.57 would pertain mostly to the supplier’s need to be accredited to enroll in Medicare.

a. Requirement of Survey (§ 424.57(c)(23))

Section 424.57(c)(23) requires all suppliers to notify their AO when a new DMEPOS location is opened. Significantly, it also states that the AO may accredit the new supplier location for three months after it is operational without requiring a new site visit. We propose to remove the latter statement from § 424.57(c)(23) because it contradicts proposed § 424.58(e)(8)(i)(A) and (C). These two paragraphs state, respectively, that unless CMS otherwise directs or permits in writing, the AO: (1) must survey all suppliers seeking accreditation or reaccreditation; and (2) cannot accredit the supplier before the survey is conducted and the AO concludes that the supplier is adherent to the quality standards. In our view, allowing a supplier to become accredited for 3 months without the important vetting of a survey and the AO’s review of the survey results presents a serious risk of beneficiary harm and improper Medicare payments, which we must prevent. Accordingly, revised § 424.57(c)(23) would be limited to stating that all suppliers must notify their AO when a new DMEPOS location is opened.

b. Accreditation Frequency (§ 424.57(c)(22) and (24))

(1) Structural Change

Section 424.57(c)(24) states that all DMEPOS supplier locations, whether owned or subcontracted, must meet the quality standards and be separately accredited in order to bill Medicare. As this requirement mirrors that in § 424.57(c)(22) to some extent, we propose to move the current language in

§ 424.57(c)(24) to § 424.57(c)(22). Revised § 424.57(c)(22) would state the following:

- All DMEPOS suppliers and all of their locations (whether owned or subcontracted) must meet the quality standards and be separately accredited to enroll in and bill Medicare.
- The accreditation must indicate the products and services for which the supplier is accredited in order for the supplier to receive payment for those products and services. (This language is in current § 424.57(c)(22).)
- An accredited supplier’s enrollment may be denied or revoked if CMS determines that it is non-compliant with the quality standards. (This language is currently in § 424.57(c)(24).)

(2) Accreditation Periods (Revised § 424.57(c)(24))

Part 488 contains several provisions regarding the frequency with which surveys must be performed. For instance:

- Section 488.5 outlines the requirements of the AO’s accreditation or reaccreditation application. Paragraph (a)(4)(i) thereof states that the AO must describe the frequency of surveys it will perform and must agree to resurvey every accredited provider or supplier within 36 months after the prior accreditation effective date.
- Sections 488.710(a), 488.730(a), and 488.1110(a) have a similar 36-month survey requirement for HHAs and hospices, respectively.

We have issued sub-regulatory guidance stating that DMEPOS suppliers, as previously noted, must undergo an unannounced survey once every 3 years following initial accreditation. However, neither § 424.57 nor § 424.58 address the frequency with which surveys must be performed or how often a supplier must be reaccredited. While, as mentioned, HHAs and hospices fall with the high-risk categorical screening level under § 424.518, we reiterate that perhaps no other provider or supplier type over the decades has been the subject of CMS’ provider enrollment program integrity efforts more than DMEPOS suppliers; as an example, DMEPOS suppliers are the only provider or supplier type that is required to acquire and maintain a surety bond as a condition of enrollment. The program integrity issues for DMEPOS suppliers very much remain, and we are concerned that performing surveys only once every 3 years provides inadequate protection for the Medicare program. As previously underscored in this section VI.B. of this proposed rule, non-compliant suppliers can endanger the Trust Funds as well as

beneficiaries. We believe the best means of ensuring supplier compliance is through closer and more frequent monitoring of suppliers. In our view, the longer a DMEPOS supplier goes without the scrutiny of a survey and reaccreditation, the greater the chances the supplier will fall out of compliance with the quality standards during this period. We also believe that more frequent surveys and reaccreditations will spur suppliers to maintain consistent adherence to the quality standards, for they will know their next survey would be much sooner than every 3 years.

Moreover, we do not believe that the 3-year survey cycle for HHAs and hospices mandates the same for DMEPOS suppliers. Each provider and supplier type and the program integrity risks they pose are different, and we must address them based on their own particulars; there is no “one-size-fits-all” approach that can be taken for all provider and suppliers. If there is a particular group of providers or suppliers that poses and has historically posed an exceptional program integrity threat to the Medicare program—and DMEPOS suppliers have presented such a threat, especially in light of the continuing fraud schemes we have seen that have not necessarily been duplicated in scope and volume with other higher risk provider and supplier types—we must take measures commensurate with the threat. Put otherwise, the frequency of surveys and other reviews must be tailored to the risk the provider or supplier type in question presents.

For these and other reasons described in this section VI.B. of this proposed rule, we propose in revised § 424.57(c)(24) that DMEPOS suppliers must be surveyed and reaccredited at least once every 12 months. We recognize that this could prove burdensome for DMEPOS suppliers, but we again emphasize the importance of protecting the Trust Funds and the health and safety of Medicare beneficiaries.

c. Changes in Majority Ownership and the “36-Month Rule”

For Medicare certified providers and suppliers, the general purpose of a state survey or accreditation review is to determine whether the provider or supplier is in compliance with its regulatorily prescribed conditions of participation or conditions of coverage (hereafter collectively referenced as CoPs). CoPs are federal requirements that a certified provider or supplier must meet to participate in the Medicare program. As they generally focus on

health and safety protections, CoPs are crucial in ensuring that providers and suppliers are legitimate, bona fide entities capable of furnishing quality care and following safety requirements. Though it is a provider enrollment provision, § 424.550(b)(1) recognizes the importance of survey and accreditation processes (hereafter sometimes collectively referenced as the “survey process”) for HHAs and hospices. They help confirm the HHA’s or hospice’s compliance with the CoPs and the quality and safety requirements they entail. To this end, § 424.550(b)(1) states if an HHA or hospice undergoes a change in majority ownership (occasionally referenced as a “CIMO”) by sale within 36 months after the effective date of the HHA’s or hospice’s initial enrollment in Medicare or within 36 months after the HHA’s or hospice’s most recent CIMO, the provider agreement and Medicare billing privileges do not convey to the HHA’s or hospice’s new owner. Instead, the prospective provider/owner of the HHA or hospice must: (1) enroll in Medicare as a new (initial) HHA or hospice; and (2) obtain a state survey or an accreditation from an approved accreditation organization. (This is sometimes referenced as the “36-month rule”). As defined in 42 CFR 424.502, a CIMO occurs when a party acquires more than a 50 percent direct ownership interest in an HHA or hospice during the 36 months following the HHA’s or hospice’s initial enrollment or most recent CIMO. CIMOs can include an acquisition of majority ownership through the cumulative effect of asset sales, stock transfers, consolidations, or mergers.

Section 424.550(b)(1) was promulgated in 2009 and modified in 2010 and 2023. There were two principal objectives behind its establishment.

First, there was a trend in the HHA community whereby an HHA applied for Medicare certification, underwent a survey, and became enrolled in Medicare, but then was immediately sold without having seen a Medicare beneficiary or hired an employee. These brokers, in other words, enrolled in Medicare exclusively to sell the HHA rather than to provide services to beneficiaries. This practice enabled a purchaser of an HHA from the broker to enter Medicare with no survey, which, in turn, sometimes led that owner to soon sell the business to another party. This “flipping” or “turn-key” mechanism, in short, was used to circumvent the survey process.

Second, we were more broadly concerned about the lack of scrutiny of

new owners as a whole, not merely in cases of flipping. We made clear in the CY 2010 HH PPS final rule (74 FR 58078) that the intent of § 424.550(b)(1) goes beyond the flipping issue.⁶⁹ We explained that if an HHA undergoes a change of ownership, CMS generally does not perform a survey pursuant thereto. CMS consequently has no sure way of knowing whether the HHA, under its new ownership and management, is compliant with the HHA CoPs. Unless CMS can make this determination, there is a risk that the newly purchased HHA, without having been appropriately vetted, will bill for services when it is out of compliance with the CoPs.⁷⁰ We had the same concerns regarding hospices, and in 2023 accordingly added hospices to § 424.550(b)(1)’s purview.

We have already discussed at length in this section VI.B. of this proposed rule the long-standing fraud, waste, and abuse risks in the DMEPOS supplier community and the threat this poses not only to the Trust Funds but also to patient safety. Enhancing this dilemma is the fact that when a DMEPOS supplier ownership change crosses the 50 percent threshold, the AO typically does not perform a survey to assess compliance with the quality standards. We therefore cannot determine whether the DMEPOS supplier under its new majority ownership will be committed to adhering to all Medicare requirements and to protecting beneficiaries. There have been a significant number of such DMEPOS supplier ownership changes over the years, many of which have occurred within 36 months of initial enrollment or the supplier’s most recent CIMO—sometimes, in fact, within only a few months of initial enrollment or the previous sale. In addition, several such cases have involved the previously mentioned flipping practice, meaning the DMEPOS supplier enrolls solely to sell the business to another party. All of these concerns mirror those behind the establishment and 2023 expansion of this “36-month rule”. Considering the very elevated program integrity risk that the DMEPOS supplier type has historically posed, it is imperative that every vulnerability we detect is properly addressed. Such a vulnerability indeed exists regarding DMEPOS suppliers no less than it did for HHAs and hospices. We must ensure that DMEPOS suppliers under their new ownership receive the same level of scrutiny that initially enrolling DMEPOS suppliers do.

⁶⁹ 74 FR 58118.

⁷⁰ Ibid.

We accordingly propose in new § 424.551 to mirror the provisions of existing § 424.550(b)(1) such that a DMEPOS supplier undergoing a CIMO must enroll as a new DMEPOS supplier and be newly accredited and surveyed under § 424.58. We also propose to do the following:

- Duplicate § 424.502's definition of change in majority ownership within § 424.551 (though slightly tailored to apply to DMEPOS suppliers).
- Revise § 424.540(a)(8) to state that CMS can deactivate the enrollment of a seller of a DMEPOS supplier if the supplier undergoes a CIMO in accordance with § 424.551. (As noted in section VI.A. of this proposed rule, § 424.540(a)(8) currently includes HHAs, and we are proposing to include hospices therein, too.)

- Add new paragraph (h) to § 424.57 to emphasize that a DMEPOS supplier must comply with the provisions of § 424.551 if it undergoes a CIMO. (This would help link § 424.57 to § 424.551.)

We note that § 424.550(b)(2) contains several exceptions to the 36-month rule. Specifically, even if an HHA or hospice undergoes a CIMO, the requirement in § 424.550(b)(1) that the HHA or hospice enroll as a new HHA or hospice and undergo a survey or accreditation does not apply if any of the following four exceptions (outlined in § 424.550(b)(1)) are implicated:

- The HHA or hospice submitted 2 consecutive years of full cost reports since initial enrollment or the last CIMO, whichever is later.
- An HHA's or hospice's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.
- The owners of an existing HHA or hospice are changing the HHA's or hospice's existing business structure (for example, from a corporation to a partnership (general or limited)), and the owners remain the same.
- An individual owner of an HHA or hospice dies.

These exceptions were added to § 424.550(b) in a final rule published in the **Federal Register** on November 17, 2010, titled, "Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices" (75 FR 70372). We promulgated them because the HHA community had expressed concerns that the 36-month rule could inhibit bona fide HHA ownership transactions; for example, prospective new owners may not wish to have to enroll as a new HHA and will therefore decline to purchase the entity. We believed that our

exceptions struck a solid balance between the need for more scrutiny of new owners via the survey process while not inadvertently obstructing legitimate transactions involving legitimate parties. As an illustration, a CIMO resulting from an internal restructuring can frequently pose less of a risk of "flipping" than an HHA that—2 months after initial enrollment—is sold to another party strictly to maneuver around the survey process. These exceptions, in our view, still soundly balance the two aforementioned considerations. We accordingly propose to duplicate existing § 424.550(b)(2)(ii) through (iv) as exceptions within proposed new § 424.551, though current § 424.550(b)(2)(i) would not be mirrored because DMEPOS suppliers do not submit cost reports.

14. Solicitation of Comments

In light of the volume of changes we are proposing to the DMEPOS accreditation program, we would appreciate feedback thereon from AOs, DMEPOS suppliers, and other stakeholders. We are particularly interested in receiving comments on the following topics addressed in this proposed rule:

- The amount and types of additional information that AOs would have to submit with their initial and reapproval applications per new § 424.58(c) and (d). For instance—

++ Whether there is data we are proposing to collect that is unnecessary, superfluous, or duplicative of other requested information; and

++ Whether there is information that should be submitted beyond what we are proposing to require.

- Whether there are any grounds beyond those proposed at § 424.58(e)(5) for which the AO should be required to deny or terminate a supplier's accreditation and, if so, what those grounds are.

- The requirement in proposed § 424.58(e)(8)(i) that, except as otherwise directed or permitted by CMS, the AO perform a survey of all suppliers seeking accreditation or reaccreditation with the AO.

- Whether there are any grounds beyond those listed in § 424.58(h), (i), and (j) for which CMS should be able to, respectively, terminate, suspend, or place on probation the AO's accreditation program and, if so, what those grounds are.

- Whether DMEPOS suppliers should be surveyed and reaccredited under § 424.57(c)(24) less frequently than every 12 months and, if so, what the

survey and reaccreditation timeframe should be.

15. Conclusion

The collection of information and regulatory impact analysis sections of this proposed rule address the net cost burden associated with our DMEPOS accreditation provisions. We project that it would exceed \$128 million annually. We understand the financial impact this could have on the DMEPOS community. However, this would be more than offset by the over \$660 million in annual savings to the Medicare Trust Funds and the taxpayers due primarily to the removal of fraudulent and non-compliant DMEPOS suppliers from the Medicare program. Of no less importance, we believe that more frequent surveys, ad-hoc surveys, and stricter requirements for AOs will encourage DMEPOS suppliers and AOs to be much more vigilant in maintaining and verifying compliance with the quality standards. To illustrate, with ad-hoc surveys, a DMEPOS supplier will not know whether or when it will be selected for such a survey, meaning that the supplier could feel compelled to never allow itself to fall out of compliance with the quality standards, even for an extremely brief period. With the quality standards being designed in large part to protect beneficiaries, we believe that greater compliance therewith could reduce risks to patients' health safety from, for example, substandard DMEPOS items, inadequate equipment instructions, and poor customer service.

We hence conclude that notwithstanding the burden associated with these requirements, the saving of potentially billions of taxpayer dollars and the preservation of beneficiary safety justify it.

C. Proposed Exemption Process for Prior Authorization of Certain DMEPOS Items (§ 414.234(c)(1) and (c)(1)(ii))

1. Background

The Comprehensive Error Rate Testing (CERT) program measures improper payments in the Medicare Fee-For-Service (FFS) program. CERT is designed to comply with the Payment Integrity Information Act of 2019 (Pub. L. 116–117). As stated in the CERT 2024 Medicare FFS Supplemental Improper Payment Data report, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) claims had an improper payment rate of 21.4 percent, accounting for approximately 6.1 percent of the overall Medicare FFS

improper payment rate.⁷¹ Over the years we have implemented conditions of payment and other requirements to decrease the improper payment rate for DMEPOS.

Currently, the scope of payment for medical supplies, appliances, and devices, including prosthetics and orthotics, are defined at 42 CFR 410.36(a) and the scope and certain conditions for payment of durable medical equipment (DME) are described at § 410.38. Medicare pays for DMEPOS items only if the beneficiary's medical record contains sufficient documentation of the beneficiary's medical condition to support the need for the type and quantity of items ordered. In addition, other conditions of payment must be satisfied for the claim to be paid. Conditions of payment vary by item but are specified in statute and in our regulations. These conditions are further detailed in our manuals and in local and national coverage determinations. Additionally, for certain DMEPOS items we require suppliers to follow a prior authorization process through which a request for provisional affirmation of coverage is submitted for review before a DMEPOS item is furnished to a beneficiary and before a claim is submitted for payment.⁷² Prior authorization plays an important role in ensuring Medicare's coverage, coding, and payment requirements are met, allowing suppliers a provisional assurance of claim coverage.

On December 30, 2015, we published a final rule in the **Federal Register** titled "Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (80 FR 81674), hereinafter referred to as the "December 2015 final rule," that established a permanent prior authorization program nationally. The December 2015 final rule was based on the authority outlined in section 1834(a)(15) of the Act, which permits the Secretary to develop and periodically update a list of DMEPOS items that the Secretary determines, based on prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items. Specifically, the December 2015 final rule established a new provision at § 414.234 that specified a process for prior authorization of DMEPOS items

frequently subject to unnecessary utilization.

In addition, § 414.234(b) details criteria needed for inclusion on the Master List of Items Potentially Subject to Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements ("Master List"). Placement on the Master List makes an item eligible for CMS to require prior authorization as a condition of payment. CMS selects items from the Master List that will require prior authorization as a condition of payment, and we publish notice of such items in the **Federal Register**.

Prior authorization supports ongoing efforts to safeguard beneficiaries' access to medically necessary items and services, while reducing improper Medicare billing and payments. This is important because documentation of practitioner involvement, including their orders for DMEPOS items and documented medical necessity (as assessed under prior authorization), is all used to support proper Medicare payment for DMEPOS items.

In the November 8, 2019, **Federal Register**, we published a final rule titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements" (84 FR 60648), hereinafter referred to as the "2019 ESRD PPS & DMEPOS final rule."

In the 2019 ESRD PPS & DMEPOS final rule, we finalized technical corrections; updates to definitions and documentation requirements; standard elements of a DMEPOS order; established one harmonized Master List; revised factors for placing an item on the Required Prior Authorization List; and established the authority to exempt compliant suppliers from the prior authorization process. We noted that we believe this exemption process meets our fiduciary obligation to protect the Medicare Trust Funds while remaining cognizant of contractor resource limitations and supplier burden. Specifically, § 414.234(c)(1)(ii) clarifies that CMS may elect to exempt suppliers from prior authorization upon

demonstration of compliance with Medicare coverage, coding, and payment rules through such prior authorization process. We did not provide specifics on this exemption process in the regulatory text. However, we received comments suggesting that prior authorization be reserved for aberrant billers and suggesting that CMS consider compliance incentives to waive prior authorization for suppliers that are compliant with billing requirements. We stated that we would consider these suggestions in future rulemaking.

2. Provisions of the Proposed Rule

Prior authorization for certain DMEPOS items ensures that Medicare beneficiaries continue to receive medically necessary items while protecting the Medicare Trust Funds from improper payments, and at the same time keeping the medical necessity documentation requirements unchanged for suppliers. We propose to add language to § 414.234(c)(1) that provides additional specificity for the exemption process in § 414.234(c)(1)(ii).

To reduce supplier burden and effectively utilize contractor resources, we propose to clarify circumstances under which CMS would exempt a supplier from the prior authorization process in newly proposed § 414.234(c)(1)(ii)(A) upon demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS withdraws the exemption. We would exempt suppliers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during an initial or periodic assessment. We believe that, by achieving this percentage, the supplier would be demonstrating an understanding of the requirements for submitting accurate claims. We do not believe it is necessary for a supplier to achieve 100 percent compliance to qualify for an exemption because unintentional and sporadic errors could occur that are not deliberate or systematic attempts to submit claims that are not payable. In addition, we propose that we would withdraw an exemption if evidence becomes available, based on a review of claims, that the supplier has begun to submit claims that are not payable based on Medicare's billing, coding or payment requirements. If the rate of non-payable claims submitted becomes higher than 10 percent during a periodic assessment, we would withdraw the exemption.

In proposed § 414.234(c)(1)(ii)(B), we would provide 60-day notice of an

⁷¹ <https://www.cms.gov/files/document/2024-medicare-fee-service-supplemental-improper-payment-data.pdf>.

⁷² https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/dmepos/downloads/dmepos_pa_required-prior-authorization-list.pdf.

exemption from mandatory prior authorization requirements. Similarly, we propose to provide 60-day notice if an exemption is withdrawn, to give the supplier time to begin submission of prior authorization requests, in compliance with mandatory requirements.

We solicit comments on these proposals.

VII. DMEPOS Competitive Bidding Program

A. Background

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary of the Department of Health and Human Services (the Secretary) to establish and implement competitive bidding programs (CBPs) in competitive bidding areas (CBAs) throughout the United States for contract award purposes for the furnishing of competitively priced DMEPOS items and services, including:

- Certain DME and medical supplies (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.
- Enteral nutrients, equipment, and supplies (enteral nutrition) described in section 1842(s)(2)(D) of the Act.
- Off-the-shelf (OTS) orthotics for which payment would otherwise be made under section 1834(h) of the Act.
- Lymphedema compression treatment items (as defined in section 1861(mmm) of the Act) for which payment would otherwise be made under section 1834(z) of the Act.

1. Benefits of the DMEPOS CBP

The DMEPOS CBP utilizes bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items and services.

The primary goal of the DMEPOS CBP is to reduce excessive Medicare payments for DMEPOS items and services by awarding contracts to a group of suppliers with the lowest bid amounts that have the capacity to furnish the items and services needed in each CBA. In accordance with section 1847(b)(2)(A)(iii) of the Act, contracts cannot be awarded if the total amounts to be paid to contract suppliers in the area are not expected to be less than the total amounts that would otherwise be paid under the DMEPOS fee schedules. Another goal is to provide the best value DMEPOS to achieve positive health outcomes for Medicare beneficiaries. In

accordance with section 1847(b)(2)(A)(i) of the Act, contracts cannot be awarded to any supplier that does not meet the quality standards established in accordance with section 1834(a)(20) of the Act. From 2011 through 2018, both of these goals were successfully accomplished for many categories of DMEPOS items and services mandated for inclusion under the program that had the highest volume in terms of total allowed charges. The DMEPOS CBP provides additional benefits that are arguably just as important as lowering excessive payment rates. In general, when the DMEPOS CBP lowers the allowed amounts paid for items and services, it decreases the incentive for committing fraud. Limiting the number of contracts awarded in a competition also reduces the number of suppliers with which a contract supplier must compete for Medicare business. The lower the number of contracts awarded, the greater the chance a supplier receiving a contract has to maintain a steady stream of business and potentially increase their volume of business. The lower the number of contract awards, the more valuable the contracts become, creating a greater incentive for bidding entities to bid more competitively.

Another important benefit of the DMEPOS CBP is that it ensures access to covered DMEPOS items and services. Pursuant section 1847(b)(3)(A) of the Act, the terms of an awarded contract requires under 42 CFR 414.422 that a contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier. For example, a supplier with a contract to furnish oxygen and oxygen equipment, a product category that includes highly profitable items like oxygen concentrators, and less profitable items like liquid oxygen, must provide access to liquid oxygen as a term of their contract. Contract suppliers may not elect to only furnish the more profitable items and services included in a product category under their contract or to only furnish the items and services to beneficiaries who are less costly to serve (due to, for example, lower shipping or delivery costs for those that live in close proximity to the contract supplier's location). In contrast, suppliers of items not included under the DMEPOS CBP are not mandated to furnish any item or service to any beneficiary. They may elect not to serve beneficiaries in hard-to-reach places or not to furnish items such as liquid oxygen and oxygen

equipment that are not as profitable as other items such as stationary oxygen concentrators.

2. Standard Payment Rules for DMEPOS Items and Services and Competitive Bidding Demonstrations

Medicare began paying for DME and orthotics (leg, arm, back, and neck braces) on a fee schedule basis beginning January 1, 1989, in accordance with section 1834(a) of the Act. The fee schedule payment rules for orthotics were subsequently relocated under new section 1834(h) of the Act. In 2001, payment on a fee schedule basis was implemented for enteral nutrition covered under the prosthetic device benefit defined under section 1861(s)(8) of the Act based on the authority provided by section 1842(s)(2) of the Act. The Medicare allowed payment amounts for these DMEPOS items and services are based on the lower of the supplier's actual charge on the claim or the fee schedule amount for the item. Prior to implementation of the fee schedules, payment for these items and services was made in accordance with the reasonable charge payment methodology mandated by section 1842(b)(3) of the Act, which based the Medicare allowed payments for these items in a given calendar year based on what suppliers charged for furnishing the items and services in the preceding calendar year. The reasonable charge payments began in 1966 and increased each year without any limit on inflation until October 1986.

The statute mandates a very specific methodology for calculating the fee schedule amounts. The fee schedule amounts for DME, which were first implemented in 1989, are based on the average of the reasonable charges paid for the item during 1986 and 1987 in each State, increased on an annual basis by covered item update factors in accordance with section 1834(a)(14) of the Act. The statewide fee schedule amounts for the contiguous United States are limited by a national ceiling and floor based on the median of the statewide fee schedule amounts (ceiling) and 85 percent of the median of the statewide fee schedule amounts (floor). The fee schedule amounts for orthotics are based on the average of the reasonable charges paid for the item during 1986 and 1987 and are increased on an annual basis by covered item update factors in accordance with section 1834(h)(4) of the Act. For areas within the contiguous United States, the fee schedule amounts are based on the average reasonable charges in ten regions of the United States. The regional fee schedule amounts are

limited by a national ceiling and floor based on 120 percent of the average of the regional fee schedule amounts across all States (ceiling) and 90 percent of the average of the regional fee schedule amounts across all States (floor). The fee schedule amounts for enteral nutrition were the nationwide fee schedule amounts from 2001 through 2015. The nationwide fee schedule amounts were based on the lower of the average of the reasonable charges paid for the item in 1995 or 2000, increased on an annual basis by update factors in accordance with section 1842(s)(1)(B) of the Act. In 2016, the fee schedule amounts for enteral nutrition were adjusted based on information from the DMEPOS CBP and converted to statewide fee schedule amounts. For items of DME and orthotics that were not paid for under Medicare during 1986 and 1987, the fee schedule amounts for the items are established using the fee schedule amounts for comparable items or supplier price lists in accordance with regulations at 42 CFR 414.238. For items of enteral nutrition that were not paid for under Medicare in either 1995 or 2000, the fee schedule amounts for the items are established using the fee schedule amounts for comparable items or supplier price lists in accordance with regulations at 42 CFR 414.112.

Complaints and reports about excessive rental payments for DME began in the 1960s and early 1970s. As early as May 1972, the idea of using competitive bidding to reduce reasonable payments was presented in a report by the Government Accountability Office (GAO), then referred to as the General Accounting Office.⁷³ In response to rapidly growing expenditures for DME in the early 1980s, CMS, then referred to as the Health Care Financing Administration, contracted with Abt Associates, Inc. to design Medicare competitive bidding demonstrations for DME, which were planned to go into effect in 1987 in nine metropolitan statistical areas (MSAs). However, Congress imposed a funding moratorium on the demonstrations before they could be implemented. Throughout the 1980s and 1990s,

excessive Medicare payments for DME continued to be the focus of reports by the Department of Health and Human Services, Office of Inspector General (OIG) and the GAO, as well as media outlets and Congressional Hearings. Section 4319 of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33) mandated demonstration projects for competitive bidding for oxygen and oxygen equipment and other Part B items and services, other than physician services. CMS contracted with Abt Associates, Inc. to design the competitive bidding demonstrations mandated by the BBA of 1997, and many aspects of the demonstrations designed in the 1980s were incorporated into the demonstrations held in Polk County, Florida, for oxygen equipment and supplies, hospital beds and accessories, enteral nutrition, urological supplies, and surgical dressings from October 1, 1999 through September 30, 2002, and in San Antonio, Texas, for oxygen equipment and supplies, hospital beds and accessories, wheelchairs and accessories, general orthotics, and nebulizer drugs from February 1, 2001, through December 31, 2002. The Medicare payment amounts under the demonstrations were lowered by approximately 19 percent. Statistical and qualitative data indicate that beneficiary access and quality of services were essentially unchanged.

The DMEPOS CBP was modeled after the successful demonstration programs from the late 1990s and early 2000s. For more information about the demonstrations, refer to the proposed rule titled, “Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues,” published in the **Federal Register** on May 1, 2006 (hereafter referred to as the “2006 proposed rule”) (71 FR 25654). During the initial development of the DMEPOS CBP, we received substantial feedback from the Program Advisory and Oversight Committee (PAOC), mandated by section 1847(c) of the Act, as amended by section 302(b)(1) of the MMA, to provide advice to the Secretary with respect to the following functions:

- The implementation of the Medicare DMEPOS CBP.
- The establishment of financial standards for entities seeking contracts

under the Medicare DMEPOS CBP, taking into account the needs of small providers.

- The establishment of requirements for collection of data for the efficient management of the Medicare DMEPOS CBP.

- The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d) of the Act), and individuals.

- The establishment of quality standards for DMEPOS suppliers under section 1834(a)(20) of the Act.

The DMEPOS CBP was initially implemented using the final rule titled, “Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues,” published in the **Federal Register** on April 10, 2007 (72 FR 17992), hereafter referred to as the “2007 final rule.” Additional changes were made to the DMEPOS CBP in subsequent rulemaking.

3. Phased In Implementation of the DMEPOS CBP

As discussed previously, section 1847(a) of the Act directs us to phase in items into the DMEPOS CBP. Section 1847(b)(3)(B) of the Act mandates that the contracts awarded to suppliers under the CBP must be recomputed not less often than once every 3 years. Section 1847(a)(1)(B) and (D) of the Act mandate the phase-in of the DMEPOS CBP in nine of the largest MSAs (known as “Round 1”) implemented on January 1, 2011, followed by 91 additional large MSAs (known as Round 2) implemented on July 1, 2013, and finally in additional areas, which do not necessarily need to be tied to MSAs. Although the DMEPOS CBP is mandated to be expanded into areas throughout the United States, no timeframe is provided for when all areas must be phased in under the DMEPOS CBP. In accordance with section 1847(a) of the Act, rural areas and areas with low population density within urban areas that are not competitive may be excluded from the DMEPOS CBP, unless there is a significant national market through mail order for a particular item or service. In accordance with this directive, we initiated several rounds of the DMEPOS CBP, as summarized in table 37:

⁷³ “Need for Legislation to Authorize More Economical Ways of Providing Durable Medical Equipment Under Medicare,” B–164031 (4), May 12, 1972.

TABLE 37: COMPETITIVE BIDDING ROUNDS AND CONTRACT PERIODS

Calendar Year	Round 1 Areas (9 Metropolitan Statistical Areas (MSAs))	Round 2 Areas (90 MSAs) and National Mail Order
2011	Round 1 1/11/2011 - 12/31/2013	--
2012		
2013		
2014	Round 1 Recompete 1/1/2014 - 12/31/2016	Round 2 & National Mail Order 7/1/2013 - 6/30/2016
2015		
2016		
2017	Round 1 2017 (recompete) 1/1/2017 - 12/31/2018	
2018		
2019	Temporary Gap Period	
2020		
2021	Round 2021 (recompets for Round 1 and Round 2) 1/1/2021 - 12/31/2023	
2022		
2023		
2024	Temporary Gap Period	
2025		

For competitions under the DMEPOS CBP prior to July 1, 2016, there were some CBAs that included MSAs that spanned multiple states. However, starting on July 1, 2016 (Round 2 Recompete), those CBAs were subdivided so that there are no multi-state CBAs. This has resulted in the DMEPOS CBP operating in 130 CBAs throughout the nation, and those CBAs contain approximately half of the enrolled Medicare Part B population. The other half of the Medicare Part B population resides in areas where the DMEPOS CBP has not yet been phased-in, including approximately 275 MSAs, which we refer to as non-competitive bidding areas (non-CBAs).

In competitions under the DMEPOS CBP prior to Round 2021, bidding entities bid for contracts for furnishing multiple items and services, identified by Healthcare Common Procedure Coding System (HCPCS) Level II codes, under several different product categories. The product categories included in the CBPs prior to and including Round 2021 are as follows.

- National Mail Order CBA: Diabetes testing supplies.
- Round 1 2017 and Round 2 Recompete: Enteral Nutrients, Equipment and Supplies; General Home Equipment and Related Supplies and Accessories (including hospital beds, pressure reducing support surfaces, commode chairs, patient lifts, and seat lifts); Nebulizers and Related Supplies;

Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories; Respiratory Equipment and Related Supplies and Accessories (including oxygen and oxygen equipment, continuous positive airway pressure (CPAP) devices, and respiratory assist devices (RADs)); Standard Mobility Equipment and Related Accessories (including walkers, standard manual wheelchairs, and standard power wheelchairs); and Transcutaneous Electrical Nerve Stimulation (TENS) Devices and Supplies.

- Round 2021: OTS Back Braces and OTS Knee Braces.

In past rounds of competition, CMS allowed a 60-day bidding window for bidding entities to prepare and submit bids. Our regulation at § 414.412 specifies the rules for submission of bids under the DMEPOS CBP. Each bid submission is evaluated, and contracts are awarded to qualified bidding entities in accordance with the requirements of section 1847(b)(2) of the Act and regulations at § 414.414, which specify conditions for awarding contracts, including a financial standard evaluation of each bidding entity that submits a bid. This process included a review of tax records, credit reports, and other financial data, which led to the calculation of a financial score, similar to processes used by lenders when evaluating the viability of a company. All bidding entities must meet the

financial standards established for the program to be offered a contract. Applying financial standards to bidding entities is needed to assess the expected financial health and quality of bidding entities, and to ensure that the selected bidding entities are able to continue to serve market demand throughout the duration of the contract period.

4. Bid Surety Bonds

Section 522(a) of the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) requires bid surety bonds and State licensure for entities submitting bids under the DMEPOS CBP and was implemented as part of the final rule titled, "Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model," published in the **Federal Register** on November 4, 2016 (81 FR

77834). Section 522(a) of MACRA added section 1847(a)(1)(G) of the Act to require bidders to submit a bid surety bond by the deadline for bid submission. We implemented section 522(a) of MACRA during the next round of competitive bidding following enactment of MACRA, which was Round 2021, even though Round 2021 began after the time period specified in the statute. Section 1847(a)(1)(H)(i) of the Act provides that in the event that a bidder is offered a contract for any product category for a CBA, and its composite bid for such product category and area was at or below the median composite bid rate for all bidders included in the calculation of the single payment amount (SPA) for the product category and CBA, and the entity does not accept the contract offered, the bid surety bond(s) for the applicable CBAs will be forfeited and the Secretary will collect on the bid surety bond(s). In instances where a bidder does not meet the bid surety bond forfeiture conditions for any product category for a CBA as specified in section 1847(a)(1)(H)(i) of the Act, then the bid surety bond liability submitted by the entity for the CBA will be returned to the bidder within 90 days of the public announcement of the contract suppliers for such product category and area. Detailed conditions of the bid surety bonds were clarified in the 2016 final rule (81 FR 77931). Implementing regulations at § 414.412(h) were later amended in the final rule titled, “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS,” published in the **Federal Register** on November 14, 2018, (83 FR 56922) to require bidders to obtain bid surety bonds, and if an entity is offered a contract for any product category for a CBA, its composite bid for such product category and area is at or below the median composite bid rate for all bidders included in the calculation of the SPA(s) for the product category/ CBA combination, and the entity does not accept the contract offered, the bid surety bond for the applicable CBA will be forfeited and CMS will collect on the bid surety bond via Electronic Funds Transfer from the respective bonding company. We believe the bid surety

bond requirement encourages all bidding entities to submit substantiated bid amounts—that is, to further prevent bidding entities from submitting a low bid amount to have a better opportunity in being offered a DMEPOS Contract.

B. Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP

In order to incentivize bidding entities to submit competitive bids and in order to ensure that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D, we are proposing to make modifications to the process for selecting the number of contract suppliers sufficient to furnish items and services in a competition and the methodology for establishing SPAs for lead and non-lead items. We also propose, in lieu of self-reported supplier capacity, to estimate supplier capacity in accordance with 42 CFR 414.414(e)(2) using data on actual contract supplier capacity from previous rounds of the DMEPOS CBP. We are soliciting comments on these proposals.

1. Background

The DMEPOS CBP is a program in which Medicare-enrolled DMEPOS suppliers submit bids and compete to receive a limited number of contract(s) to furnish DMEPOS items and services, identified by HCPCS codes, within different product categories in different CBAs throughout the nation. The bids from contract suppliers under the program are used to calculate SPAs to pay the contract suppliers in lieu of the payment amounts they would otherwise receive under the standard payment rules under sections 1834(a)(2) through (7), 1834(h), 1834(z), and 1842(s) of the Act. Section 1847(b)(5) of the Act provides that Medicare payment for competitively bid items and services is equal to 80 percent of the applicable SPA, less any unmet Part B deductible described in section 1833(b) of the Act. The contract supplier collects a coinsurance payment from the beneficiary equal to 20 percent of the applicable SPA as well as any unmet Part B deductible. The total payment made to the contract supplier by Medicare and the beneficiary cannot exceed the SPA. For DMEPOS items and services that are not paid for under the DMEPOS CBP, a non-participating supplier has the option to collect more than the Medicare allowed amount from the beneficiary, a practice referred to as balance billing. Balance billing is not allowed under the DMEPOS CBP.

a. Rules in Effect Prior to Round 2021 of the DMEPOS CBP

In accordance with the 2007 final rule (72 FR 17992), prior to Round 2021, bidding entities submitted a bid amount for each item in a product category. These bid amounts were combined into one composite bid for each bidding entity, aggregating their bids for all items in a product category. To compute a composite bid, historical DMEPOS utilization data was used to assign weights to each item in each product category based on the national volume of the item in proportion to the national volume of all items in the product category. The composite bid for a bidding entity equaled the item’s weight multiplied by the item’s bid amount and summed across all items in the product category, which was used to determine the expected costs for all items in the product category based upon expected volume. Once a composite bid was calculated for each entity that submitted a bid in the competition, the composite bids were arrayed in order from lowest to highest. CMS began the contract award process by awarding a contract to the supplier with the lowest composite bid and then awarding contracts to the next supplier in the array. This process was repeated until there were enough suppliers to meet the projected demand⁷⁴ in the CBA for the items in the product category. The composite bid for the bidding entity where the cumulative capacity of the bidding entities for furnishing the items and services meets or exceeds projected demand is referred to as the pivotal bid. The array of bidding entities with bids at or below the pivotal bid are referred to as the winning contract suppliers or the winning array of suppliers. The bids for these contract suppliers are used to establish the SPAs for the items and services in the product category for each CBA.

Prior to Round 2021, the SPA for each item in the product category was calculated based on the median of the winning contract suppliers’ bids for each item. As explained in the 2007 final rule, we believed that setting the SPA based on the median of the contract suppliers’ bids satisfies the statutory requirement that SPAs are to be based on bids submitted and accepted. This resulted in a single payment for an item under a DMEPOS CBP that was representative of all acceptable bids, not just the highest or the lowest of the

⁷⁴ As explained in the 2007 DMEPOS final rule (72 FR 18039), demand for items and services was projected using Medicare claims data for allowed services during the previous 2 years, trended forward to the contract period.

winning bids for that item (72 FR 18045). Using the median of the winning bids as opposed to the lowest or highest bids is consistent with how Medicare has established allowed payment amounts for DMEPOS items since the beginning of the Medicare program. Under the reasonable charge payment methodology in place from 1966 through 1988, payment was based on the lower of the supplier's customary charge (the 50th percentile of charges from the supplier), or the prevailing charge for the item (the 75th percentile of customary charges for the item from suppliers in a given locality). The fee schedule amounts used to pay claims for DMEPOS beginning in 1989 are based on average reasonable charges for the items. The lowest or highest charges for an item were never used to establish the Medicare allowed payment amount for the DMEPOS item.

At the start of the DMEPOS CBP in 2011, CMS inflated demand for items and services in the CBAs so that more contracts would be awarded than needed to better ensure access to items and services under the new program. Prior to the finalization of the median of winning bids methodology, CMS explained to its Program Advisory and Oversight Committee that although a number of suppliers will be paid below what they bid, an approximately equal number of suppliers will be paid more than they bid.⁷⁵

From the inception of the DMEPOS CBP in 2011 and implementation of subsequent rounds through 2018, CMS implemented a very successful program using item weights, composite bids, and SPAs that were based on the median of the winning contract suppliers' bids for each item. Using the median of the winning bids resulted in 40 to 80 percent reductions in payment amounts under the program, even though more contracts were awarded than needed to meet an inflated demand target for items and services, because use of the median of winning bids reduces the impact of "outlier" bids at the top and bottom of the array of winning bids on the payment amount established for all contract suppliers. Suppliers accepted their contract offers at the median of the

winning supplier bids approximately 92 percent of the time consistently from round to round, Medicare and taxpayers saved money, and access to quality items and service was preserved. Section 1834(a)(1)(F) of the Act requires CMS to adjust fee schedule amounts for DME items and services furnished in non-CBAs based on the SPA pricing. Sections 1834(h)(1)(H)(ii) and 1842(s)(3)(B) of the Act provide discretion to adjust fee schedule amounts for OTS orthotics and enteral nutrition, respectively, furnished in non-CBAs based on SPA pricing. Adjustments to the fee schedule amounts have been in place for these items and services for several years and contract suppliers have accepted payment at the adjusted rates as payment in full for approximately 99 percent of all claims with no significant downward trends in utilization, and no negative changes in beneficiary health outcomes, as determined by CMS's health outcome claims monitoring.

b. Changes Implemented with Round 2021 of the DMEPOS CBP

Significant changes to the DMEPOS CBP were made as part of the final rule entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS" published in the **Federal Register** on November 14, 2018 (83 FR 56922) to improve the competitiveness and sustainability of the program. Effective January 1, 2019, and beginning with Round 2021, a "lead item" pricing methodology was established for submitting bids, calculating composite bids for bidding entities, determining pivotal bids, and calculating SPAs. The methodology for calculating SPAs was changed from the median of the winning contract suppliers' bid amounts for each item in the product category to the maximum winning contract supplier bid amount for a "lead item" in the product category, which is used to calculate the SPAs for all items in the product category. Under these rules, instead of submitting bid amounts for each item in the product category, the bidding entity submits a single bid amount for a "lead item" in the product category and this bid amount represents the bidding entity's "composite bid" for

furnishing all items in the product category. The "lead item" in each product category is defined in our regulations at § 414.402 to mean the item, in a product category with multiple items, with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition. The bids for the lead item are used to establish the SPAs for both the lead item and all other items (non-lead items) in the product category. In accordance with § 414.416(b)(1), the SPA for a lead item furnished under a CBP is equal to the maximum bid amount submitted for that item by bidding entities whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. Additionally, under § 414.416(b)(2), the SPA for a lead item must be less than or equal to the amount that would otherwise be paid for the same item under the DMEPOS fee schedule. The SPAs for the non-lead items within the product category are determined by multiplying the lead item SPA by a relative ratio. The ratios are based on the historic differences in the fee schedule amounts for the lead item and non-lead items. In accordance with § 414.416(b)(3), the SPA for a non-lead item in a product category furnished under a CBP is equal to the SPA for the lead item in the same product category multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, and the United States Virgin Islands) for the non-lead item divided by the average of the 2015 fee schedule amounts for all areas for the lead item.⁷⁶

The lead item pricing methodology was adopted to prevent a phenomenon that had been occurring under the DMEPOS CBP known as "unbalanced bidding," where bidding entities submitted low bid amounts for higher volume items under the product category because these bid amounts had a greater impact on their composite bid, and higher bid amounts for lower volume items under the product category because these bid amounts had a lesser impact on their composite bid. This resulted in skewed pricing results where SPAs for lower cost items with fewer features such as a manual hospital bed without side rails were higher than SPAs for higher cost items with more features such as a semi-electric hospital bed with side rails. Lead item pricing maintains the historic differences in

⁷⁵ As required by section 1847(c) of the Act, the Secretary of Health and Human Services established the Program Advisory and Oversight Committee (PAOC), which advised the Secretary on a range of implementation topics for the DMEPOS CBP. The PAOC comprised of a broad mix of relevant industry, consumer, and government parties. Specifically, the membership included beneficiary/consumer representatives, manufacturer representatives, supplier representatives, certification/standard representatives, Federal and State program representatives, a physician and a pharmacist.

⁷⁶ Calendar year 2015 is the last year the fee schedule amounts were not adjusted based on information from the CBP.

prices for these items, while streamlining the bidding process and significantly decreasing the burden for bidding entities since they only have to submit one bid amount for each competition (product category and CBA). Previously, the bidding entity had to submit bid amounts for every item in the product category, which for some product categories such as standard power wheelchairs and standard manual wheelchairs was over a hundred separate bid amounts.

c. Projecting Demand for Items and Services and Estimating Supplier Capacity for Furnishing Items and Services

In determining the number of contract suppliers for a competition, we aim to limit the number of contract suppliers to ensure they are incentivized to submit a competitive bid. As discussed in section B.1.d. of this proposed rule, awarding too many contracts decreases the incentive for a bidding entity to submit a competitive bid—given that bidding entities would be more likely to be awarded a contract regardless of the submitted bid amount. At the same time, in determining the number of contracts to award in a competition, we balance a number of other considerations set forth at sections 1847(b)(2)(A)(iv) and (b)(4)(B) of the Act. Section 1847(b)(4)(A) of the Act, allows the Secretary to limit the number of contract suppliers in a CBA to the number needed to meet projected demand for items and services covered under the contracts and also directs the Secretary to consider whether the bidders can furnish enough items or services to meet the anticipated needs of individuals within the contract's geographic area on a timely basis. Section 1847(b)(4)(B) of the Act also specifies that the Secretary shall award contracts to multiple entities submitting bids in each area for an item or service and section 1847(b)(2)(A)(iv) of the Act specifies that individuals must have access to multiple contract suppliers in the CBA or else contracts may not be awarded in that area. In balancing these considerations, we codified in current regulations at 42 CFR 414.414(e) our process for selecting the number of contract suppliers to be awarded a contract for a competition.

From 2011 through 2023, the methodologies and procedures used for projecting demand for items and services and estimating a supplier's capacity for furnishing items and services as a contract supplier remained virtually unchanged. These methodologies were designed to overestimate demand and underestimate

capacity to ensure access under the program when it began. These methodologies inflated the projected demand target for items and services, awarded no capacity for contract suppliers new to an area or product category, and limited a contract supplier's estimated capacity to their historic levels if they did not meet certain financial standards. Soon after the program was implemented in 2011, it was apparent that more contracts were being awarded under the program than needed to meet demand for items and services; however, CMS decided to continue using these methodologies during each round of competition up to and including Round 2021. While more contracts were awarded than needed to meet demand, this was balanced by establishing SPAs using the median of winning bids rather than a higher amount such as the maximum winning bid, thus still achieving the goal of lowering payment amounts and achieving savings under the DMEPOS CBP.

Under current regulations at 42 CFR 414.414(e)(1), which were revised as part of the November 14, 2018, final rule (83 FR 57018), we first calculate the expected beneficiary demand in the CBA for the lead item in the product category. This methodology accounts for actual historic beneficiary utilization of the lead item in the product category prior to each round of the DMEPOS CBP, while also considering the expected growth in the number of Medicare beneficiaries in the CBA as well as the expected growth in utilization of the lead item in the product category in the CBA. Specifically, under this methodology, CMS calculates the projected beneficiary demand for the lead item by multiplying the actual historic beneficiary utilization by a percent increase that is derived from increasing historic utilization by both the expected increase in number of beneficiaries and the expected increase in utilization, in general. If either the change in number of beneficiaries or the change in utilization in the CBA is expected to be negative, the negative trend is not included in the projection of demand and is instead set equal to one. In addition, the projected beneficiary demand is not reduced based on the number of items that would likely be furnished by grandfathered suppliers, which typically furnish approximately 15 percent of rented durable medical equipment items and related accessories (83 FR 57024). In accordance with section 1847(a)(4) of the Act and regulations at 42 CFR 414.408(j),

suppliers of rented DME and oxygen and oxygen equipment can become “grandfathered suppliers” and continue furnishing these items under the DMEPOS CBP if the rental agreement or supply arrangement with the beneficiary began prior to the start of the contract period. CMS has thus inflated the demand target in order to provide more contract suppliers for beneficiaries to choose from by using historic utilization, trending this forward by both the expected increase in number of beneficiaries and the expected increase in utilization and by not decreasing the number to account for fraudulent claims, decreases in the number of beneficiaries, or the percentage of demand that is accounted for by grandfathered suppliers or other non-contract suppliers under the exceptions at 42 CFR 414.404(b) for physicians, hospital outpatient departments, physical therapists, and occupational therapists. In the past, this did not compromise savings under the program when the median of winning bids was used to establish SPAs rather than a higher payment such as the maximum winning bids.

After determining the projected beneficiary demand, pursuant to 42 CFR 414.414(e)(2), we then calculate the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the lead item in the product category. The capacity is currently based on the bidding entity's self-reported projection of how many items they could furnish at the amounts they bid. If a bidding entity reported a capacity that was less than their historic capacity, the capacity for the bidding entity was adjusted up to the level of their historic capacity; however, the capacity was never increased above their historic capacity.

Pursuant to 42 CFR 414.414(e)(5), CMS then analyzes each eligible bidder's financial health to assess its ability to furnish its estimated capacity against the projected beneficiary demand in each competition.

- If a bidder's financial score⁷⁷ meets the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount, CMS accepts the bidder's capacity at the greater of its estimated or historical capacity (based on claims

⁷⁷ CMS uses the required tax return extract and the required financial documents to calculate standard accounting ratios for each bidder. These ratios, along with the credit report and numerical credit score or rating, are used to compute the bidder's financial score. The methodology for computing bidders' financial scores has remained consistent throughout all rounds of the DMEPOS CBP.

data). However, if a bidder's financial score does not meet this threshold, the bidder is a new supplier (does not have 12 months of actual financial statements and submits at least one month of pro forma statements), or the bidder is a specialty supplier, CMS only accepts its capacity at its historical amount.

- If a bidder's accepted capacity is greater than 20 percent of projected beneficiary demand in the CBA, CMS adjusts the bidder's capacity to 20 percent of projected beneficiary demand to ensure at least five contracts are awarded for each competition, in accordance with 42 CFR 414.414(h).

Pursuant 42 CFR 414.414(e)(3) and (4), we then array the composite bids from the lowest composite bid price to the highest composite bid price and calculate the pivotal bid for the product category using the projected beneficiary demand and supplier demand calculated in accordance with 42 CFR 414.414(e)(1) and (2), as discussed previously. The pivotal bid, as defined under 42 CFR 414.402, is the lowest composite bid based on bids submitted by bidding entities for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category. In accordance 42 CFR 414.414(e)(5), contracts are awarded to all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category (and that meet the supplier eligibility requirements specified in the regulations and the *Request for Bids Instructions*) are selected as winning contract suppliers for the competition.

In order to ensure that the number of contract suppliers selected will meet beneficiary demand, CMS conducts a secondary analysis to determine if additional contract suppliers should be awarded contracts. Part of this analysis examines if bidding entities awarded contracts need (and are planning) to expand operations and need time to ramp up to meet projected beneficiary demand. To do so, CMS analyzes the most recent 12 months of claims data that was not available when we first conducted this analysis for all contract suppliers that should be awarded contracts under the initial analysis. Using this data allows CMS to account for any unforeseen increases in utilization as almost a year has passed since the original calculation of the projected beneficiary demand. This secondary analysis further scrutinizes bidders' capacity to confirm that they are capable of furnishing items at levels exceeding their historical capacity in the competition prior to calculating the final SPAs. Beginning with Round 2021,

bidders were no longer required to submit expansion plans as part of this process in accordance with the calendar year 2019 final rule titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS" and published in the **Federal Register** on November 14, 2018 (83 FR 56922). This is performed by separating bidders into three groups that factor in each bidder's financial health, experience furnishing the lead item, and ramp-up revenue percentage.⁷⁸ Expansion plans were required in rounds prior to Round 2021 for suppliers that were new to an area, new to a product category, or submitted an estimated capacity that represented substantial growth over current levels.

Group 1:

- Meets the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount; and

- Has experience furnishing the lead item in the CBA; and

- Has sufficient ramp-up revenue.

CMS accepts the higher of the estimated or historical capacity for Group 1 bidders.

Group 2:

- Meets the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount; and

- Does not have experience furnishing the lead item in the CBA, but has experience furnishing the lead item in other CBAs for which the bidder has submitted a bid; and

- Has sufficient ramp-up revenue.

CMS uses an experience factor to determine the capacity for Group 2 bidders by dividing the CBAs in which a bid was submitted where the bidder has experience furnishing the lead item by the total CBAs in which a bid was submitted for the lead item.

⁷⁸ Ramp-up revenue is determined by multiplying a bidder's projected growth (that is, taking the bidder's estimated capacity minus its historical capacity) by the preliminary SPA for the lead item. To determine if a bidder has sufficient ramp-up revenue to support its estimated capacity, its ramp-up revenue is divided by the bidder's actual revenue to produce a percentage. The purpose of this process is to act as a safeguard to ensure bidders are not over-estimating their ability to expand.

Group 2 bidders will have their capacity adjusted by multiplying the bidder's estimated capacity, in each of the competitions where they do not have experience, by the experience factor. For example, if a bidder submitted 10 bids for enteral nutrition and only had experience in half of those competitions, the bidder would have its estimated capacity lowered by 50 percent for the competitions where it does not have experience.

Group 3:

- Does not meet the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount; or

- Is a new supplier or a specialty supplier; or

- Does not have experience furnishing the lead item in any CBA for which the bidder has submitted a bid; or

- Does not have sufficient ramp-up revenue

CMS accepts the historical capacity for Group 3 bidders, which is zero for bidders with no experience furnishing the lead item.

As initially stated, it is important to note that this secondary analysis is only used as a method for offering additional contracts and will not remove any bidding entities from the initial winning array (that is, bidding entities whose bids were at or below the pivotal bid). That is, the pivotal bid amount set during the initial capacity analysis is never lowered, even if this secondary analysis determines that beneficiary demand can be met with fewer suppliers. As a result, this secondary analysis removes the 20 percent of projected beneficiary demand limit (explained in the second bullet in step 1 noted previously) because Step 1 already ensures that at least five contracts are awarded for each competition in accordance with § 414.414(h).

If the secondary analysis determines that no additional bidders are needed to meet beneficiary demand, the preliminary SPAs established under the initial analysis are set as the final SPAs for the competition as explained in the next section. However, if the secondary analysis determines that additional bidders are needed to meet beneficiary demand, CMS continues through the array (bidders that are eligible for a contract offer are arranged by lowest to highest lead item bid amount) until bidder capacity meets or exceeds beneficiary demand for the competition. Once CMS adds enough bidders to where the cumulative accepted capacity of the bidders selected in the array meets beneficiary demand, the pivotal

bid is increased accordingly, and the resulting SPAs are set as the final SPAs for the competition.

As established in at 42 CFR 414.416(b)(1) the SPA for a lead item furnished under a competitive bidding program is equal to the maximum bid submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. Once the pivotal bid is determined and the selection of winning contract suppliers is finalized, the SPAs are calculated based on the maximum submitted bid amount of contract suppliers in the winning array.

In order to ensure that small suppliers, meaning a supplier generates gross revenue of \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue, have an opportunity to be considered for participation under the CBP in accordance with section 1847(b)(6)(D) of the Act, the special rules at § 414.414(g) establish a goal of awarding at least 30 percent of the total number of contracts to small suppliers. CMS then determines which percentage of bidders in the winning array of bids are small suppliers. If less than 30 percent, CMS will offer a contract to the next eligible small supplier(s) until the 30 percent small supplier target is reached or there are no more eligible small suppliers for the competition. Additional contracts may be awarded when a bid disqualification is overturned. Additional contracts may also be awarded if needed to meet demand when a contract offer is declined. Finally, in accordance with § 414.414(i), additional contracts may be awarded after CMS initially awards contracts, if necessary, to meet demand.

d. Problems Associated With Awarding More Contracts Than Needed To Meet Demand for Items and Services

The current process for calculating total supplier capacity in accordance with 42 CFR 414.414(e)(2), which is calculated based upon the supplier's estimated capacity levels once awarded a contract, and for projecting beneficiary demand in accordance with 42 CFR 414.414(e)(1), which, as described previously is inflated above historic levels even in situations where the Medicare fee-for-service beneficiary population is declining in the CBA, results in the awarding of significantly more contracts than needed to meet actual demand for items and services in the CBA. Although access to multiple suppliers is mandated by section 1847(b)(2)(A)(iv) of the Act, awarding an excess number of contracts can reduce

the competitiveness of the program, which results in higher payment amounts—hurting potential savings. Large suppliers especially have limited to no incentive to submit competitive bids in such an environment (where excessive numbers of contracts are awarded). To highlight this issue, take for example if there were only two or three very large national chain suppliers that were all awarded contracts in most of the CBAs from 2011 through 2018, it is possible that any one of these suppliers alone would have been able to meet most of the actual demand for the particular item or service in many of the CBAs. For example, if two chain suppliers become contract suppliers for a competition round after round regardless of what bid amount they submit, they would learn that they could submit a bid amount that is higher than they would be willing to accept and still be added as a contract supplier for the competition, which in turn would have a negative impact on savings under the competition. We observed this issue in the Round 2 Recompete (2016). We found that on average, 13 contracts were awarded per competition, but typically 4 contract suppliers were sufficient to meet the beneficiary demand in the CBA for the lead item in the product category. In general, 4 of the selected contract suppliers had no utilization and 5 of the contract suppliers had low utilization (that is, furnishing items and services to less than 5 percent of the applicable beneficiary population). Most DMEPOS product categories have historically been dominated by a few large national chain suppliers, and we have seen a downward trend in the total number of suppliers and more concentration among the large suppliers in terms of volume and market share. From 2022 to 2024, the number of medical supply companies enrolled as DMEPOS suppliers decreased by 7 percent from 6,438 to 5,973. Over this same 2-year period, Medicare Part B enrollment also decreased by 5 percent from 35.3 million to 33.4 million, while the number of allowed services attributed to enrolled DMEPOS suppliers grew from 1.97 billion to 2.11 billion. While savings were generally favorable under this approach, this evidence indicates that future competitions would have been increasingly strained to recompile items and services.

2. Current Issues

The lead item pricing and maximum winning bid amount SPA methodologies were implemented under Round 2021 of the DMEPOS CBP (refer to table 37 for an explanation of the CBP rounds). CMS

competed 16 product categories in 130 CBAs in Round 2021, although the product category for non-invasive ventilators was removed in April 2020 following the exercise of the Defense Production Act due to the coronavirus disease 2019 (COVID-19) PHE. Of the remaining 15 product categories, 13 were included in previous rounds of the CBP, while OTS back and knee braces were competed for the first time. Within the 130 CBAs, there were over 2,000 competitions and CMS received and reviewed over 49,000 bids. The Round 2021 contracts went into effect in 127 CBAs for the OTS back braces and OTS knee braces product categories, resulting in estimated Medicare savings of \$934 million. Pursuant to 42 CFR 414.414(f), CMS announced that it would not award competitive bidding contracts for 13 product categories for Round 2021 that were previously competed because the payment amounts did not achieve expected savings.⁷⁹

The competitions for contracts in Round 2021 were largely unsuccessful in achieving savings because the methodology for calculating SPAs was changed from the median of winning bid amounts used in previous rounds to the maximum winning bid amount, but CMS made no changes to how the number of contracts awarded in a competition is calculated. As discussed, the current process for selecting the number of contracts to award results in significantly more contracts than needed to meet actual demand for items and services in the CBA and this process has resulted in higher payment amounts than the payment amounts that would have been established if the number of contracts was limited to the number needed to meet actual demand for items and services in the CBA. By calculating SPAs based on the maximum bid amount submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category, CMS began setting payments based on the highest of the bid amounts from suppliers not needed to meet the demand for items and services in the CBA. In addition, these maximum winning bid amounts were often an outlier price (a bid amount from a single bidding entity that is significantly higher than the bid amounts from other bidding entities). Consequently, adjusting the methodology for setting the SPA without adjusting the number of contracts awarded eliminated the

⁷⁹ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Round-2021>.

ability of the program to achieve savings because the SPAs that would have been used to pay contract suppliers would have resulted in total payments to contract suppliers that greatly exceeded the total amounts that would otherwise be paid. When the maximum winning bid amount is used to establish the SPA	rather than a bid amount from lower in the winning array of bidders, it is more likely that an outlier bid amount will be selected as the SPA, which is problematic. Table 38 shows the actual bid amounts submitted for a Round 2021 competition (the competition is not	identified to protect the confidentiality of the bidding entities). The bid amounts are for the bidding entities that would have been awarded contracts based on the current methodologies for projecting demand and determining supplier capacity for meeting demand. BILLING CODE 4120-01-P

TABLE 38: BID AMOUNTS FOR BIDDING ENTITIES IN “WINNING RANGE” FOR SAMPLE ROUND 2021 COMPETITION

No. in Array	Bid Amount	Note
36	\$189.00	Maximum winning bid amount
35	\$150.00	
34	\$135.00	
33	\$131.66	
32	\$124.00	
31	\$120.00	
30	\$120.00	
29	\$114.95	
28	\$110.00	
27	\$105.00	
26	\$99.88	
25	\$99.00	
24	\$98.00	
23	\$97.97	
22	\$94.64	
21	\$89.95	
20	\$89.00	
19	\$83.78	
18	\$81.75	Median – \$82.76
17	\$78.90	
16	\$77.64	
15	\$77.62	
14	\$72.07	\$74.25 = 2021 Amount Otherwise Paid
13	\$69.50	
12	\$68.00	
11	\$65.52	
10	\$65.00	
9	\$62.99	
8	\$62.37	
7	\$62.00	
6	\$61.88	
5	\$60.00	
4	\$60.00	
3	\$59.90	
2	\$53.29	
1	\$41.00	

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Pursuant to 42 CFR 414.414(f), contracts were not awarded for this product category and CBA because the total payments that would have been

made to contract suppliers based on the maximum winning bid amount of \$189.00 would have greatly exceeded the payment amounts that would have otherwise been made at \$74.25, the

adjusted fee schedule amounts calculated in accordance with 42 CFR 414.210(g)(10) using bid amounts from previous rounds of competition. This table shows the impact of outlier pricing

on the SPA that results when using the maximum winning bid method. The maximum winning bid of \$189 is \$39 and 26 percent higher than the next highest bid of \$150. This real-life scenario demonstrates that just adding one additional bidding entity has a significant impact on the amount that all the contract suppliers would be paid, particularly when their bids do not include capacity numbers above their historical norms. In contrast, the median of winning bids is right in the middle of the array of bids and is not affected greatly by the outlier bid of \$189. Removing the bidding entity with the \$189 bid from the array only decreases the median by one dollar from \$82.76 to \$81.75. In this specific example, had the number of contracts awarded been limited to 14 rather than 36, then the payment amount would have been lower than the amount that would otherwise have been paid and contracts could have been awarded (assuming no other proposals in this rule were otherwise adopted and only the median bid methodology was in effect). Of the 36 bidding entities in this example, 9 were new bidding entities and the policy for new bidding entities is to count their capacity as zero, meaning they were not needed to meet demand. An additional 13 bidding entities did not indicate that they could expand their capacity beyond historic levels if awarded a contract. Removing 22 bidding entities from the list of winning range suppliers (the nine new bidding entities and the 13 bidding entities that indicated they could not expand their capacity) coincidentally leaves 14 bidding entities in the winning range. In order to have successful competitions in the future, the number of contracts awarded and the methodology used to establish the payment amounts made to the contract suppliers must result in total payments to contract suppliers that do not exceed the amounts that would otherwise be paid, after also factoring in the impact of the CBP in reducing fraud, waste, and abuse as discussed in greater detail in section VII.D., titled "Bid Limits and Conditions for Awarding Contracts if Savings are Not Expected."

The goal in this proposed rule is to find the right mix in terms of the number of contracts awarded and how to establish the SPAs using the bid amounts so that contracts are awarded to multiple suppliers but no more than needed to meet beneficiary demand for items and services, and to ensure the DMEPOS CBP will generate total payments to contract suppliers that are less than the total amounts that would otherwise be paid under the standard

payment rules under sections 1834(a)(2) through (7), 1834(h), 1834(z), and 1842(s). As noted previously, CMS must be cognizant of how the SPA methodology and methodology to select the number of awarded contracts can impact whether total payments to contract suppliers that are less than the total amounts that would otherwise be paid under these standard payment rules.

As explained in more detail later in this section, we believe certain changes to how CMS determines the number of awarded contracts and changes to the SPA methodology can increase the likelihood that the DMEPOS CBP program will generate savings. Regarding changes to how CMS determines the number of awarded contracts, we believe data on actual contract supplier capacity from previous rounds of the DMEPOS CBP should be used in lieu of self-reported supplier capacity estimates CMS uses, in accordance with 42 CFR 414.414(e)(2), to determine the number of contracts needed to meet demand for items and services in a CBA.

Three options for determining SPAs are discussed later in this section and address how the number of contract suppliers would need to be limited in order to achieve savings at the median bid level if bid amounts higher than the median bid amounts are used to establish the SPA. These options include using the median of winning bid amounts, using the maximum winning bid amount but limiting the number of contract suppliers so that the maximum winning bid amount is approximately equal to the median of winning bid amounts, or using the 75th percentile of winning bid amounts but limiting the number of contract suppliers so that a maximum winning bid amount is approximately equal to the median of winning bid amounts. In addition to the change described previously, we evaluate how complementary changes to the methodology for calculating number of awarded contracts may or may not affect the competitiveness of the program. One option is to use the median of winning bids (median bid option). The second option is to continue using the maximum winning bid (maximum bid option) and limit the number of contracts awarded so that the maximum winning bid is approximately equal to where the median of winning bids would be under the median bid option. The third option, which we believe is the best approach, is to establish SPAs based on the 75th percentile of winning bids (75th percentile option) and limit the number of contracts awarded so that

the 75th percentile of winning bids is approximately equal to where the median of winning bids would be under the median bid option. Using the 75th percentile approach pays more contract suppliers above their bid amount than below their bid amount, which was a criticism of the median bid option, and is less susceptible to outlier pricing than the maximum bid option.

Conceptually, where the SPA is based on the maximum winning bid rather than the median of winning bids, many contract suppliers are paid using a SPA that is significantly higher than the bid amount they submitted, therefore providing more money for them to furnish additional items and services (that is, to increase their capacity) and resulting in the need for fewer contract suppliers.

Round 2021 was not successful for the 13 product categories included under the CBP from 2011 through 2018 with SPAs calculated based on the median of winning bids in those previous competitions. CMS did not change the methodology for determining the number of contracts to award, continuing the practice of awarding more contracts than needed to meet demand, even though the bid amount used for calculating SPAs was changed from the median of winning bids to the maximum winning bid. If, in addition to adjusting the SPA methodology, CMS had revised the methodology for determining the number of contracts to award so that less contracts were awarded, it would have been more likely that the maximum winning bid amounts would have been closer to the median of winning bid amounts in prior rounds. This is important because the fee schedule amounts for items included in prior competitions had already been adjusted in accordance with section 1834(a)(1)(F) of the Act based on the SPAs calculated using the median of winning bids, becoming the payment amounts that would otherwise be paid in the absence of implementation of the DMEPOS CBP. Under the requirements for awarding contracts under section 1847(b)(2)(A)(iii) of the Act, total payments to contract suppliers based on SPAs must not be expected to exceed the total amount that would otherwise be paid. Contracts could not be awarded under Round 2021 if the SPAs based on the maximum winning bids were significantly higher than the SPAs previously established for the items and services based on the median of winning bids, as this would have resulted in total payments to contract suppliers being greater than the adjusted fee schedule amounts that would

otherwise be paid. As explained later in this section, this problem was further compounded by bidding entities submitting lower capacity estimates than in previous rounds of competition, with very few bidding entities providing estimates that they could increase their volume of business and market share if awarded a contract.

Prior to the opening of the bid window for Round 2021, CMS published a “Capacity and Demand” Fact Sheet to increase transparency regarding the DMEPOS CBP by explaining the methodology that CMS would utilize to calculate projected beneficiary demand for Round 2021, as well as how CMS would determine a bidder’s capacity to meet projected demand. CMS also provided increased transparency by publishing a “Financial Scoring Methodology” Fact Sheet that explained how bidding entities would be evaluated to determine if they met the financial standards mandated by section 1847(b)(2)(A)(ii) of the Act. After receiving this detailed information, some industry consultants created and distributed information encouraging bidding entities to submit very low estimates of their capacity to furnish items if awarded a contract in order to significantly overinflate the total number of contracts awarded and drive up the maximum winning bids and SPAs. For example, when bidding to become contract suppliers for oxygen and oxygen equipment, 56 percent of the bidding entities “estimated” they could furnish less than one percent of the projected first year demand target and 1,496 out of 3,192 (47 percent) bidding entities submitting oxygen bids in Round 2021 “estimated” that they would not be able to provide one additional oxygen concentrator a month beyond what they have historically furnished. Also, 261 out of 3,192 (8 percent) bidding entities submitted an estimated capacity of one concentrator a month. This is the lowest possible capacity number a bidding entity could provide as their estimated capacity because the DMEPOS Bidding System would not allow an estimated capacity entry of zero.

After the Round 2021 bid evaluation processes concluded, we estimated that if payments had been made using SPAs based on the maximum winning bids, this would have resulted in an increase of \$1.2 billion in total payments to contract suppliers above the total amounts that would otherwise have been made over the 3-year contract performance period for Round 2021. As a result, CMS was prohibited from awarding contracts, per section 1847(b)(2)(A)(iii) of the Act, in all

product categories except OTS back braces and OTS knee braces, which saved an estimated \$934 million. The OTS back braces and OTS knee braces product categories were new, and payment using the SPAs based on maximum winning bid amounts did result in lower payments to contract suppliers than would otherwise be made in most of the 130 CBAs. We found as a result of this effort that the practice of providing very low-capacity estimates as part of the bid in order to increase SPAs affects the calculation of the SPA regardless of whether the SPA is based on the maximum winning bid amount or the median of winning bid amounts, but the effect is much more pronounced and subject to outlier bids when the SPA is based on the maximum winning bid. A median is calculated using all bids (low and high), whereas the maximum winning bid is based on one bid amount (the highest) and can change dramatically from one bidding entity to the next as shown in table 38.

Very low bidding entity-reported estimates of their capacity for furnishing items would have resulted in the award of more contracts than needed to meet demand. The combination of the awarding of more contracts than needed to meet demand and the change in determining SPAs to use of the maximum winning bid in Round 2021 resulted in an inability to award contracts for almost all items and services because total payments to contract suppliers would have greatly exceeded payments that would have otherwise been made. It is therefore important to establish a more accurate methodology for determining the number of contract suppliers needed to incentivize competitive bids and meet projected demand for items and services, and to select a methodology for determining SPAs that does not result in situations where total payments to contract suppliers would exceed payments that would otherwise be made. Furthermore, CMS does not have a mechanism to address situations where bidding entities submit capacity estimates that do not accurately reflect their ability to increase their volume of business if awarded a contract. As seen in the bids for Round 2021, this resulted in capacity estimates that were arbitrary and would have resulted in an increase in the number of contracts awarded and thereby drive up the prices paid under the program. In order for pricing to be competitive, especially as markets consolidate and small suppliers may not be expanding their businesses, the number of contracts awarded has to be limited to the degree that large suppliers

face the risk of not being awarded a contract, thereby creating an incentive to bid more competitively. Only a small number of bidders were excluded in past rounds of competition, greatly reducing the incentive for suppliers to bid competitively. Thus, we believe the methodology for determining the number of contracts to award for future rounds of the DMEPOS CBP cannot rely on self-reported capacity estimates from bidding entities as this methodology is not effective in limiting the number of contracts awarded to the number needed to meet projected demand for items and services in accordance with section 1847(b)(4)(A) of the Act.

In order to successfully recompete contracts for product categories previously bid under the methodology that established SPAs based on the median of winning bid amounts in accordance with section 1847(b)(2)(A)(iii) of the Act, there must be an expectation that total payments to contract suppliers will be less than the total amounts that would otherwise be paid. We have explored and summarized three options, which have been informed by simulations we conducted using bid and contracting information from previous rounds of the DMEPOS CBP. We explain additional details about these simulations in a later discussion.

The first possible option of accomplishing this is to implement the methodology for determining SPAs used under competitions prior to Round 2021 that established SPAs based on the median of winning bid amounts, and award the same number of contracts awarded under those pre-Round 2021 competitions, adjusted based on the percentage change in Medicare Part B enrollment in the CBAs. We refer to this as the “median bid” option.

A second option would be to maintain the current methodology that establishes SPAs based on the maximum winning bid amount. Based on our analysis of past bidding rounds, we believe that to meet the requirements of section 1847(b)(2)(A)(iii) of the Act and maintain the current methodology for determining SPAs based on maximum winning bid amounts, we would need to better ensure that the maximum winning bid amount is closer to the median winning bid amount that would be selected under the first option. We believe this could be achieved by reducing the number of contracts awarded under future competitions by approximately 50 percent below the number of contracts awarded in past bidding rounds. This would reduce the likelihood of basing the SPA on an outlier bid amount and could increase

the likelihood that the SPAs established under this option would be roughly equivalent to the SPAs that would be established under the median bid option. We refer to this as the “maximum bid” option.

A third option would be to implement a methodology that uses the 75th percentile of winning bid amounts to establish a SPA, which is halfway between the median or 50th percentile of winning bid amounts and the maximum winning bid amount or 100th percentile of winning bid amounts. Similar to the process discussed for the second option, based on our analysis of past bidding rounds, we believe that to meet the requirements of section 1847(b)(2)(A)(iii) of the Act we would need to implement a process to better ensure that the selected bid amount is not influenced by outlier bid amounts and remains closer in value to the amount that would be selected under option one. We believe this could be

achieved by reducing the number of contracts awarded under future competitions by approximately 25 percent below the number of contracts awarded in past bidding rounds. This would reduce the likelihood of basing the SPA on an outlier bid amount and better increase the likelihood that the SPAs established under this option would be roughly equivalent to the SPAs that would be established under the median bid option. We refer to this as the “75th percentile” option.

Reducing the number of contracts awarded in proportion to the position in the array of winning contract suppliers used to establish the SPA is necessary in order to comply with the requirements of the statute. Section 1847(b)(3)(B) of the Act requires that contracts be recompeteted not less often than once every 3 years, while section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under these competitions unless the total amounts to

be paid to contract suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. Establishing SPAs using bid amounts from suppliers higher in the array of winning contract suppliers than the median of bid amounts increases the chances that the SPA will be based on an outlier price (a bid amount that is significantly higher than other bid amounts for contract suppliers in the winning array), and therefore increases the chances that the competitions will not be successful in generating payments that are less than the amounts that would otherwise be paid for the items and services. These risks must be considered to implement future competitions under the DMEPOS CBP that are successful in generating program savings for competitively priced DMEPOS items and services. Table 39 lists the three options discussed previously and the tradeoffs associated with each option.

TABLE 39: THREE OPTIONS FOR DETERMINING SPAS

SPA	Tradeoffs
Median Bid	• Highest number of winners and choice of contract suppliers and lowest risk of outlier prices • Approximately half of winning contract suppliers with bid amounts below SPA
75 th Percentile	• Lower number of winners and greater risk of outlier prices than median bid option • More contract suppliers paid at or above their bid amount than median bid option
Maximum Bid	• Lowest number of winners and greatest risk of outlier prices • All contract suppliers paid at or above their bid amount

The median bid option offers the highest number of contracts for suppliers, and, therefore, the greatest degree of choice for beneficiaries. Even though this option results in payment amounts that are higher than the bid amounts for approximately half of the suppliers in the winning array of bidding entities, much criticism has been provided by DMEPOS suppliers, manufacturers, and certain economists about the fact that this option results in payment amounts that are lower than the bid amounts for approximately half of the suppliers in the winning array of bidding entities. Despite that criticism suppliers accepted the contracts at the median SPA rates 92 percent of the time and as noted previously, beneficiary access was not compromised, suppliers in non-CBAs adjusted to using these rates, assignment rates remained high, and beneficiary health outcomes remained stable. Nevertheless, as noted previously, we were seeing some pressures in downward trends in regard to suppliers’ willingness to expand capacity, indicating that the current

structure might not have been sustainable for the long term.

The maximum bid option, which would base SPAs on the maximum winning bid amounts coupled with an approximate 50 percent reduction in the number of contracts awarded below past bidding rounds, offers the lowest number of contracts for suppliers, and, therefore, the smallest degree of choice for beneficiaries. While this option results in payment amounts that are equal to or higher than the bid amounts for all of the suppliers in the winning array of bidding entities, even with a reduction in the number of contract suppliers, it also presents the highest risk of establishing a SPA based on an outlier bid, resulting in a SPA that might not meet the statutory requirement for total payments to contract suppliers that are lower than the total amounts that would otherwise be made for the items and services in the CBA. We observed this in Round 2021. We believe the risk of additional unsuccessful competitions using this option is too great.

The 75th percentile option uses the bid amount in the array of winning bid

amounts that is halfway between the median of the winning bid amounts (50th percentile) and maximum winning bid amount (100th percentile) to establish the SPA, and, therefore, serves a “middle ground” option. This option would be coupled with an approximate 25 percent reduction in the number of contracts awarded below past bidding rounds. It therefore results in more contracts and less risk of outlier prices than the maximum winning bid option, but fewer contracts and more risk of outlier prices than the median bid option. It is also an option that has never been attempted under the DMEPOS CBP. This option partly addresses the criticism provided by DMEPOS suppliers, manufacturers, and certain economists about paying contract suppliers less than their bid amount. However, as noted previously, the fact that 92 percent of suppliers accepted contracts at the median bid rates, and these amounts were proven to be adequate for items and services to be furnished with no negative impact on health outcomes, indicates that this criticism may be unfounded. While

there is still a greater risk of outlier prices associated with this option than the median bid option, we believe this option would result in successful competitions, and we are soliciting comments on a proposal that this methodology replace the current maximum bid methodology in the regulations for calculating the SPAs for items and services under the CBP. In order for this option to enable the DMEPOS CBP to meet its statutory objectives, the number of contracts awarded must be reduced by approximately 25 percent from the current methodology so that total payments to contract suppliers based on SPAs equal to the 75th percentile of winning bid amounts are no greater than total payments to contract suppliers based on SPAs equal to the median (or 50th percentile) of winning bid amounts. We continue to maintain that, "One of the purposes of the program is to create a competitive bidding payment structure that is more reflective of a competitive market" (72 FR 18036).

We analyzed the performance of contract suppliers under the previous Round 2 Recompete and Round 1 2017 competitions and identified the number of contract suppliers in each competition that provided at least 5 percent of total contract supplier utilization during these rounds of competition. We believe these numbers represent the number of contract suppliers that made a meaningful contribution toward meeting demand for the items and services in each competition. Under the previous Round 2 Recompete and Round 1 2017 competitions, on average, only 28 percent of contract suppliers furnished at least 5 percent of the total number of items and services furnished by contract suppliers in each competition. This indicates that the vast majority of contracts awarded under these previous rounds were not necessary to ensure access and that there is sufficient experience and rationale for reducing the number of contracts offered under the DMEPOS CBP to determine a competitive price while maintaining access as mandated by section 1847(b)(4)(A) of the Act.

If under future competitions, the number of contracts awarded for each

competition was limited to the number of contract suppliers that furnished at least 5 percent of the total number of items and services for the competition, this would reduce the number of contract suppliers in the winning array and increase the likelihood that total payments to contract suppliers under future rounds of competition would be lower than the amounts that would otherwise be paid. If we continue awarding the same number of contracts as in past rounds of competition and use the 75th percentile of winning bid amounts rather than the 50th percentile (median) of winning bid amounts to establish the SPAs, the SPAs would be prohibitively higher than they would otherwise be if we had used the median of winning bid amounts to establish SPAs. To counter this, we can reduce the number of contracts awarded so that the 75th percentile of winning bid amounts are more closely aligned to where the median of winning bid amounts would have fallen. Using the competition example under table 38, the 75th percentile of the 36 bid amounts is \$105.00, which is much higher than the median of winning bid amounts of \$82.76. Under this competition, if the number of suppliers in the winning array is reduced by 25 percent from 36 to 27, the 75th percentile of the 27 bid amount amounts is \$89.95, which is only 9 percent higher than the median of winning bid amounts of \$82.76. However, there is no way to know for sure if the contract suppliers in the winning array under future competitions with this type of cap on the number of contracts awarded would have the capacity to furnish all of the items and services needed in the competition. Although larger suppliers should have economies of scale that would allow them to bid lower than smaller suppliers, it is possible that all large suppliers could be outbid by small suppliers that collectively do not have the capacity to meet demand for the items and service covered under their contracts. We are therefore soliciting comments on a proposal to increase the number of contracts awarded to double the number of contract suppliers that previously furnished at least 5 percent of the items and services needed in the competition. This would mitigate the

risk of awarding too few contracts such that the total supplier capacity would not be sufficient to meet the expected beneficiary demand, but would also increase the risk of awarding too many contracts, resulting in situations where total payments to contract suppliers at the 75th percentile of winning bid amounts could be greater than the payments that would otherwise be made based on fee schedule amounts adjusted using information from past rounds of the CBP where SPAs were established based on the median (or 50th percentile) of winning bid amounts rather than the 75th percentile of winning bid amounts.

CMS contracted with the Research Triangle Institute (RTI) to evaluate how the changes in Round 2021 impacted the DMEPOS CBP, and to consider ways in which the DMEPOS CBP can address the issues that occurred in Round 2021. RTI conducted a simulation of the 75th percentile option using bid and contracting information from previous rounds of the DMEPOS CBP. Specifically, RTI used the number of Round 2 Recompete and Round 1 2017 contracts in each of these successful competitions, as well as Round 2 Recompete and Round 1 2017 contract supplier utilization, to determine the number of contract suppliers that furnished at least 5 percent of total contract supplier utilization under each under these previous rounds. These numbers were then doubled to generate the target number of suppliers to include in the winning array in each competition under the simulation. The SPAs for the lead item in each competition were calculated based on the 75th percentile of bid amounts for suppliers in the winning array. If the 75th percentile fell directly on one of the suppliers in the winning array, that bidding entity's bid amount became the SPA for the competition under the simulation. Table 40 provides an example of this calculation. If the 75th percentile fell between 2 bidding entities (that is, there was an odd number of bids in the winning array), the SPA was determined using the amount that is 75 percent between the two bid amounts, rounded to the nearest cent. An example of this calculation is provided in Table 41.

TABLE 40: EXAMPLE OF CALCULATING THE 75TH PERCENTILE WHEN FALLING ON ONE SUPPLIER

Winning Contract Suppliers	Bid Amount
1	\$4.00
2	\$5.00
3	\$5.25
4	\$5.50
5	\$6.00
6	\$6.50
7	\$7.00
8	\$7.50

The 75th percentile falls directly on the sixth winning supplier (8 × 75 percent = 6), resulting in the SPA of \$6.50.

TABLE 41 EXAMPLE OF CALCULATING THE 75TH PERCENTILE WHEN FALLING BETWEEN TWO SUPPLIERS

Winning Contract Suppliers	Bid Amount
1	\$4.00
2	\$5.00
3	\$5.25
4	\$5.50
5	\$6.00
6	\$6.50
7	\$7.00
8	\$7.50
9	\$8.00

The 75th percentile falls between the 6th and 7th winning supplier with bid amounts of \$6.50 and \$7.00, respectively. The SPA is calculated using the amount that is 75 percent of the way between \$6.50 and \$7.00, rounded to the nearest cent, which is \$6.88 ($[(\$7.00 - \$6.50) * 75 \text{ percent}] + \$6.50$).

After the SPAs were calculated, additional contracts were added for small suppliers, if necessary, to meet the 30 percent small supplier target in each competition.

The last step of the simulation involved a review of the utilization for the suppliers that would be awarded contracts in each competition under the simulation to determine if their combined historic capacity totaled at least 5 percent of the overall utilization for the lead item in the competition. If the suppliers that would be awarded contracts did not collectively provide at least 5 percent of the overall utilization for the lead item in the competition, one additional bidding entity that met all eligibility requirements as stated in the request for bids for the competition and furnished at least 5 percent of the overall utilization in the competition for

the lead item, was awarded, if available. If bidding entities met these criteria, the bidding entity with the lowest bid amount was awarded a contract under the simulation.

The resulting SPAs and total number of contracts awarded under the simulation were then compared to the SPAs and total number of contracts awarded under the previous Round 2 Recompete and Round 1 2017 competitions. In 91 percent of the simulated competitions (1,539 of 1,690), both the SPAs and number of contracts awarded were lower than the SPAs and number of contracts awarded under Round 2 Recompete and Round 1 2017. Of the remaining 151 simulated competitions, 10 competitions resulted in the same number of contracts being awarded under Round 2 Recompete and Round 1 2017 competitions, while three competitions resulted in more contracts being awarded. Additionally, of the 151 simulated competitions, 105 competitions had higher SPAs than the Round 2 Recompete and Round 1 2017 competitions, while 41 competitions had SPAs that were the same as the Round 2 Recompete and Round 1 2017 competitions. Please note that there is

overlap in how the simulation data for the remaining 151 competitions is presented. For example, a simulated competition that resulted in more contracts and a higher SPA compared to a Round 2 Recompete and Round 1 2017 competition could be counted in both the contract and SPA data mentioned previously.

In order to ensure beneficiary access to items and services under the simulation, a floor on the total number of contracts awarded was established, so that the number of contracts awarded under the simulation would be no less than 50 percent of the number of contracts awarded under the previous rounds, rounded up to the nearest whole number. Also, in order to ensure savings under the simulation, a ceiling on the total number of contracts awarded was established, so that the number of contracts awarded under the simulation would be no more than 75 percent of the number of contracts awarded under the previous rounds, rounded down to the nearest whole number. Note that modifications to the methodology for determining the number of contracts to award for product categories that have never been

included under the CBP, as well as the product categories for OTS back braces and OTS knee braces included in Round 2021, are discussed later in this section. The simulation was run again using the floor and ceiling, and the results were analyzed. The simulated SPAs were mostly lower than the SPAs under the previous Round 2 Recompete and Round 1 2017 competitions. For all

product categories and CBAs for both the Round 2 Recompete and Round 1 2017 competitions, the percentage reduction in the number of contracts awarded ranged from 33 percent for enteral nutrients, equipment, and supplies, to 41 percent for standard manual wheelchairs. In addition, the percentage reduction in SPAs ranged from 2.6 percent for hospital beds to

13.8 percent for group 2 support surfaces. To illustrate the results of the simulation, the simulation SPAs and number of contract suppliers is compared to the number of contracts and SPAs for Round 1 2017 for oxygen and oxygen equipment (lead item, HCPCS Level II code E1390) in Table 42.

TABLE 42: ROUND 2017 RESULTS COMPARED WITH SIMULATION RESULTS FOR OXYGEN AND OXYGEN EQUIPMENT (LEAD ITEM HCPCS LEVEL II CODE E1390)

CBA	2017 # of Contracts	2017 SPA	75 th # of Contracts	75 th SPA	Reduction in # of Contracts	Reduction in SPA
Charlotte-Concord-Gastonia, NC	21	\$79.00	14	\$72.33	33%	8%
Chester, Lancaster & York Counties, SC	15	\$70.04	11	\$70.00	27%	0%
Cincinnati, OH	21	\$79.00	12	\$76.21	43%	4%
Cleveland-Elyria, OH	25	\$78.00	16	\$77.42	36%	1%
Covington-Florence-Newport, KY	18	\$72.45	11	\$69.81	39%	4%
Dallas-Fort Worth-Arlington, TX	31	\$76.48	22	\$72.90	29%	5%
Dearborn, Franklin, Ohio & Union Counties, IN	15	\$74.92	9	\$70.09	40%	6%
Kansas City-Overland Park-Ottawa, KS	18	\$79.23	12	\$73.91	33%	7%
Kansas City, MO	19	\$78.53	13	\$73.91	32%	6%
Miami-Fort Lauderdale-West Palm Beach, FL	29	\$90.01	16	\$82.99	45%	8%
Orlando-Kissimmee-Sanford, FL	23	\$79.20	12	\$72.00	48%	9%
Pittsburgh, PA	28	\$77.50	20	\$70.71	29%	9%
Riverside-San Bernardino-Ontario, CA	21	\$79.22	13	\$70.77	38%	11%

Under the simulation, there was a 36 percent average reduction in the number of contracts awarded for oxygen and oxygen equipment in the Round 1 2017 CBAs under the simulation and a 6 percent average reduction in the SPAs. For comparison, the percentage of contract suppliers in each Round 2 Recompete and Round 1 2017 competition that furnished 5 percent or more of total contract supplier utilization was, on average, only 28 percent suggesting that the number of contracts awarded but not needed in a competition in the previous rounds was as high as 72 percent. Thus, we believe a reduction in the number of contracts awarded under the DMEPOS CBP of approximately 36 percent would not result in a shortage of contract suppliers.

We acknowledge the simulation uses supplier bids from past competitions and does not reflect how suppliers may

actually bid in future competitions. However, we believe the balance of achieving savings while ensuring access to items and services under the program would be preserved if these changes are implemented. The suppliers competing for contracts would know that only a limited number of contracts would be offered, and we believe this would increase the level of competition under the program in terms of lower bid amounts that also result in adequate payment for all contract suppliers, while also mitigating some of the concerns of the supplier community associated with using the median winning bid.

If the maximum bid option were used, the reduction in the number of contracts awarded would need to be even greater, such as no more than 50 percent of the number of contracts awarded in the previous rounds of competition. Using the maximum bid option would mean

fewer suppliers would be awarded contracts than under the other two options, providing less choice for beneficiaries and increasing the chances that the amount paid is an outlier price that is significantly higher than the bid amounts of other winning contract suppliers. Using the median bid option would minimize or eliminate the impact of outlier prices but would result in more contract suppliers being paid less than the amount they bid. We are not proposing either of these options, but we are soliciting comments on these two options in addition to the proposed 75th percentile option. A summary of how the number of contracts to award in the next competition for items included in Round 2 Recompete, Round 1 2017, and Round 2021 of the DMEPOS CBP would be determined under the three options is summarized in Table 43.

TABLE 43: THREE OPTIONS FOR DETERMINING SPAS AND NUMBER OF CONTRACTS TO AWARD FOR PRODUCT CATEGORIES AND CBAS INCLUDED IN ROUND 2 RECOMPETE, ROUND 1 2017, AND ROUND 2021 OF THE DMEPOS CBP

SPA	Number of Winning Contract Suppliers for Next Competition
Median Bid Alternative	The number of winning contract suppliers is equal to the total number of contract suppliers from the last successful competition (regardless of the quantity of items furnished by each contract supplier), adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023 for OTS back braces and OTS knee braces.
75 th Percentile Proposal	The number of winning contract suppliers is equal to double the number of Round 2 Recompete, Round 1 2017, or Round 2021 contract suppliers that furnished at least 5 percent of the total utilization for the lead item in the competition, adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023 for OTS back braces and OTS knee braces. The total number of contracts awarded would be no less than 50 percent of the number of contracts in Round 2 Recompete, Round 1 2017, or Round 2021 rounded up to the nearest whole number and no more than 75 percent of the number of contracts in Round 2 Recompete, Round 1 2017, or Round 2021 rounded down to the nearest whole number.
Maximum Bid Alternative	The number of winning contract suppliers is equal to 50 percent of the total number of contract suppliers in Round 2 Recompete, Round 1 2017, or Round 2021 (regardless of quantity of items furnished by each contract supplier), adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023 for OTS back braces and OTS knee braces.

As an example of how this would work for the 75th Percentile Proposal, in 2018, CMS had 29 contract suppliers to furnish continuous positive airway pressure (CPAP) items in the Miami, FL competitive bidding area, but only 9 contract suppliers furnished at least 5 percent of the total utilization for CPAP in the Miami, FL CBA. If Part B enrollment for the area has decreased by 5 percent since 2018, the CMS would do the following:

- Double the number of contract suppliers in 2018:
 $9 \times 2 = 18$
- Adjust the result by the 5 percent decrease in Part B enrollment since 2018:
 $18 \times 0.95 = 17.1$ rounded to the nearest whole number, 17.
- Determine the fewest number of contracts to award:
 $29 \times 0.50 = 14.5$ rounded up to the nearest whole number, 15.
- Determine the highest number of contracts to award:
 $29 \times 0.75 = 21.75$ rounded down to the nearest whole number, 21.
- Compare the result in Step 2 to the fewest and highest number of contracts and adjust up or down, if necessary:
 No change needed as 17 is greater than 15 and less than 21.

Result: CMS would award 17 contracts for CPAP in the Miami, FL CBA.

In addition, as explained earlier, we are not proposing any changes to the method of using the lead item to establish pricing under current regulations at 42 CFR 414.416, but are proposing to change the methodology used for determining SPAs for lead

items under § 414.416(b)(1) to replace “maximum bid” with “75th percentile of bids”.

We are also soliciting comments on our proposal to change the way the SPAs are calculated for the non-lead items in a product category. Currently, to calculate the non-lead item, CMS multiplies the lead item SPA by a relative ratio, which is based on the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, the United States Virgin Islands) for the non-lead item divided by the average of the 2015 fee schedule amounts for all areas for the lead item. This formula uses average fee schedule amounts, which in some cases results in SPAs for non-lead items being higher than the fee schedule amount that would otherwise be paid because the 2015 fee schedule amounts for some areas are lower than the average of the 2015 fee schedule amounts for all areas. To address this situation for CBAs other than a nationwide or regional CBA, we are soliciting comments on a proposal to calculate the ratio based on the 2015 fee schedule amounts for each specific area rather than the average of the 2015 fee schedule amounts for all areas. For example, in the Miami/CPAP competition, the lead item SPA for the CPAP product category will be multiplied by a relative ratio, which will be based on the 2015 fee schedule amount for the CPAP non-lead item in Miami divided by the 2015 fee schedule amount for the CPAP lead item in Miami. For nationwide or regional CBAs, we would still need to use the average of the fee schedule amounts since these CBAs would include

multiple areas with different fee schedule amounts.

For all three options, the number of winning contract suppliers for all subsequent competitions would be provided to bidders prior to bidding. For example, based on the Miami/CPAP 75th percentile option example noted previously, we would let bidding entities know that for the initial competition for these items last furnished by contract suppliers in 2018, a total of 17 contracts would be awarded for this competition. The SPA for the lead item would be based on the 75th percentile of the bids for the 17 lowest bidding entities for the CPAP product category in Miami. For subsequent rounds of competition, the number of contracts awarded would be based on the number of winning contract suppliers from the initial competition under the new rules (17 in this example), trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the last contract period. We are soliciting comments on a proposal to slightly modify versions of the methodology discussed previously for determining the number of contracts to award for product categories that have not previously been included under the DMEPOS CBP. For product categories or CBAs that were not included in Round 2 Recompete, Round 1 2017, or Round 2021 of the DMEPOS CBP, the proposed methodology for determining the number of winning contract suppliers in the next competition under the 75th percentile option, as well as the alternative options, are described in table 44.

TABLE 44: DETERMINING SPAS AND NUMBER OF CONTRACTS TO AWARD FOR NEW PRODUCT CATEGORIES AND CBAs PHASED IN TO THE DMEPOS CBP

SPA	Number of Winning Contract Suppliers for Next Competition
Median Bid Alternative	The number of winning contract suppliers is equal to 150 percent of the number of suppliers that furnished at least three percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, rounded up to the nearest whole number.
75 th Percentile Proposal	The number of winning contract suppliers is equal to 125 percent of the number of suppliers that furnished at least three percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, rounded up to the nearest whole number.
Maximum Bid Alternative	The number of winning contract suppliers is equal to the number of suppliers that furnished at least three percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, rounded up to the nearest whole number.

The number of winners for the 75th percentile option would be 25 percent lower than the median option and 25 percent higher than the maximum option, which is in proportion to the percentage increase in the position in the winning array of bid amounts where the SPA would be set using the median option (50th percentile) and the percentage decrease in the position in the winning array of bid amounts where the SPA would be set using the maximum option (100th percentile). The number of winning contract suppliers for competitions following the initial competition under the new rules would be based on the number of winning contract suppliers from the initial competition under the new rules, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the last contract period. For new product categories and CBAs, we use 3 percent of total utilization for the lead item rather than 5 percent as the measure of a contract supplier that made a meaningful contribution toward meeting total demand for the lead item. We believe the measure of meaningful supplier performance should be different for product categories and areas that have never been included under the CBP because there is no limit on the number of suppliers that can furnish items and services; therefore, spreading out overall utilization of the items and services over more contract suppliers. As noted previously, under the previous Round 2 Recompete and Round 1 2017 competitions, on average, only 28 percent of contract suppliers furnished at least 5 percent of the total number of items and services furnished by contract suppliers in each competition. For new product categories there is no limit on the number of suppliers furnishing items like there is under the DMEPOS CBP and therefore our claims data shows less concentration and a lower average volume of items furnished per

supplier. However, data indicates that generally, there have been the same dominant, local suppliers in the competitive bidding areas providing the majority of DMEPOS, even prior to the implementation of the DMEPOS CBP.

We can illustrate how we would determine the number of contracts to award for new product categories being phased into the DMEPOS CBP using 2023 Medicare claims data. If competitions were held today for a nationwide remote item delivery (RID) CBP as proposed under section F using the 75th percentile methodology, then based on 2023 Medicare claims data for the lead items for the examples of potential future product categories in Table 45 entitled “Categories of Items Furnished from Remote Supplier Locations”, we would award the following numbers of RID CBP contracts: seven for urological supplies; eight for ostomy supplies; nine for class II continuous glucose monitors (CGMs); nine for OTS upper extremity braces; nine for OTS back braces; and 10 for OTS knee braces. By comparison, 11 contracts were awarded for the Round 2 Recompete national mail order CBP for diabetes testing supplies. Five contract suppliers furnished at least 3 percent of total contract supplier utilization (allowed services) for diabetes testing supplies. These five suppliers accounted for 92 percent of total contract supplier utilization (allowed services) from July 1, 2016, through December 31, 2018.

There could be situations where CMS is not able to award enough contracts to meet the target number of contracts in a competition, if for example, the target number of contracts for the competition is 10, but only five entities submitted a bid. In these instances, CMS plans to move forward with awarding contracts to all eligible bidding entities in the competition, as long as there are at least 2 or more eligible bidding entities to award contracts to, and we do not otherwise have data indicating that the

bidding entities that would be awarded contracts would not be able to meet beneficiary demand. Once the competition is implemented, CMS will monitor for any potential access concerns, as it has done continually since 2011 (even during temporary gap periods in the DMEPOS CBP).

Finally, current regulations at 42 CFR 414.414(h) indicate that contracts are generally awarded to at least five suppliers satisfying the conditions for awarding contracts under § 414.414(b) through (f). As the program is implemented in additional areas throughout the United States, we believe that five contract suppliers would be excessive for some areas and product categories. Therefore, in addition to proposing to revise the regulations to include the methodologies described previously for determining the number of contract suppliers needed for each competition, we are proposing to indicate that this number can be no lower than 2 for any competition as the statute mandates multiple contract suppliers (at least 2), per section 1847(b)(4)(B) of the Act. We are soliciting comments on these proposals.

3. Provisions of the Proposed Regulation

In the previous section, we discussed three options to calculate the SPAs for items and services under the CBP (the current maximum bid methodology, the median bid methodology used in prior rounds of the CBP, and a 75th percentile methodology). Based on that discussion we are soliciting comments on our proposal to:

- Change the methodology used for determining SPAs for lead items under the program by revising § 414.416(b)(1) to replace “maximum bid” with “75th percentile of bids,” so that the SPA for the lead item in the product category would be based on the 75th percentile of bid amounts for the lead item that are equal to or below the pivotal bid for the product category.

- Revise § 414.416(b)(1) to indicate that in cases where there is an odd number of winning contract suppliers and the 75th percentile falls between 2 suppliers, the SPA for the lead item would be determined by going 75 percent of the way between the 2 bid amounts, rounded to the nearest cent.
- Change the way the SPAs are calculated for the non-lead items in a product category in CBAs other than a nationwide or regional CBA by revising § 414.416(b)(3). Specifically, the calculation would involve multiplying the lead item SPA by a relative ratio, which would be based on the 2015 fee schedule amount for the non-lead items in the applicable state divided by the 2015 fee schedule amounts for the lead item in the applicable state.
- Change the methodology for calculating the number of contract suppliers sufficient to furnish items and services in a competition by revising § 414.414(h). Specifically, for competitions included in the DMEPOS CBP in 2018 or 2023, the first time a competition is recompeted after 2023, the number of contract suppliers selected to furnish items and services would be at least 2, but no more than double the number of contract suppliers that furnished at least 5 percent of total allowed services for the lead item furnished by contract suppliers to the applicable beneficiary population during 2018 or 2023, adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023. The number of suppliers awarded contracts would not be less than 50 percent of the total number of contract suppliers in 2018 or 2023 rounded up to the nearest whole number, or more than 75 percent of the total number of contract suppliers in 2018 or 2023 rounded down to the nearest whole number. After the first time a competition is recompeted after 2023, the number of contract suppliers selected to furnish items and services would be equal to the number of contract suppliers selected the first time a competition is recompeted after 2023, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the most recent contract period.

For competitions not included in the DMEPOS CBP in 2018 or 2023, the first time a competition is conducted after 2023, the number of contract suppliers needed to furnish items and services would be at least 2, but no more than 125 percent of the number of contract suppliers that furnished at least 3 percent of total utilization for the lead item in the product category and CBA

during the most recent calendar year at the time of bidding. For all subsequent recompetes for the competition, the number of contract suppliers needed to furnish items and services would be equal to the number of contracts awarded the first time a competition is held after 2023, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the most recent contract period.

In previous sections we proposed using contract supplier capacity data from previous rounds of the DMEPOS CBP, as opposed to using supplier-reported capacity, to determine the number of contract suppliers needed to meet demand for items and services in a CBA. Therefore, we are proposing to change the methodology for evaluating bids by revising § 414.414(e). Specifically, CMS is proposing to evaluate composite bids submitted for a lead item within a product category by: (1) calculating the number of contract suppliers selected to furnish the items and services in the competition based on the methodology described previously, (2) arraying the composite bids from the lowest composite bid price to the highest composite bid price and (3) selecting the number of contract suppliers and networks that were calculated in #1 that meet basic supplier eligibility, quality standards and accreditation, and financial standards. We are soliciting comments on this proposal.

C. Adjustments to SPAs

CMS recognizes the increased challenge a supplier may have to account for the potential future effects of price increases when formulating its bids. We are soliciting comments on our proposal to apply an annual update factor to SPAs as we believe it would give bidding entities more certainty and confidence in formulating their bids based on their costs at the time of bidding, and would help ensure beneficiary access in the event that costs do increase significantly during a contract performance period.

1. Background

The fee schedule amounts for DME, orthotics, and enteral nutrition are updated by annual update factors specified in sections 1834(a)(14), 1834(h)(4)(A), and 1842(s)(1)(B) of the Act, respectively. The payment amounts for lymphedema compression treatment items are updated on an annual basis in accordance with regulations at 42 CFR 414.1650(c). In general, the annual update factors are established based on the percentage change in the Consumer

Price Index for all Urban Consumers (CPI-U) calculated by the Bureau of Labor Statistics for the 12-month period ending with June of the previous year, although for certain years, the statute has mandated a “freeze” or zero percent update, or other percentage below the percentage change in the CPI-U, for DME, orthotics, and enteral nutrition. In addition, for 2011 and subsequent years, the update factors for DME, orthotics, and enteral nutrition are reduced by a productivity adjustment, which in some years can result in a negative percentage or reduction in the fee schedule amounts.

In the 2006 proposed rule (71 FR 25663), we proposed to apply an annual inflation update to the SPAs established for a CBP (proposed 42 CFR 414.408(b)). Specifically, beginning with the second year of a contract entered into under a CBP, we proposed to update the SPAs by the percentage increase in the CPI-U for the 12-month period ending with June of the preceding calendar year. We stated that using the CPI-U index would be consistent with Medicare using this index to update the DME fee schedule and would obviate the need for the bidding entity to consider inflation in the cost of business when submitting its bids for furnishing competitively bid items under a multiyear contract. We did not finalize the proposal to apply an annual inflation update to SPAs. In the 2007, final rule (72 FR 18005), we stated that we believe it is more appropriate for bidding entities to address the possible effects of inflation or price increases when they formulate their bids because automatic payment adjustments to competitively bid items may result in higher payment amounts than would occur under the DMEPOS fee schedule payment amounts if these amounts are subject to legislative freezes or payment reductions.

2. Current Issues

As a result of the COVID-19 PHE, supply chain disruptions, and recent years’ higher than normal inflation, we believe it would improve the CBP to add an annual inflation update to the SPAs as long as the updates are the same as the updates to the DMEPOS fee schedule amounts, which would prevent the SPAs from becoming higher than the fee schedule amounts during a contract period of 2 or 3 years in length. CMS has recognized the increased challenge a bidding entity may have to account for the potential future effects of price increases when formulating its bids. We believe that adding an annual update factor would address unforeseen changes and inflation as described previously, giving bidding entities more

certainty and confidence in formulating their bids based on their costs at the time of bidding. We believe this would reduce burden for bidding entities since they would no longer need to factor standard inflationary cost increases into their bid calculation. We also believe it would help to better ensure access to items and services under the program in the event that costs do increase significantly during the contract period.

3. Provisions of the Proposed Regulation

We are proposing to amend 42 CFR 414.408 by revising paragraph (b) and its title to adjust the SPAs for the second and third years of a DMEPOS CBP supplier contract performance period by an inflation update equal to the percentage change in the CPI-U for the 12-month period ending 6 months prior to the beginning of the respective second or third year of the DMEPOS CBP supplier contract performance period. We propose that in no case could the updated SPA for an area be greater than the unadjusted fee schedule amount for the state or area that includes the CBA where the SPA is applied or 110 percent of the adjusted fee schedule amount for state or area that includes the CBA where the SPA is applied. We are soliciting comments on this proposal.

D. Bid Limits and Conditions for Awarding Contracts if Savings Are Not Expected

Recognizing that the DMEPOS CBP generates additional savings for Medicare beyond reducing the payments amounts for DMEPOS items and services, we propose that in determining whether the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid, in accordance with section 1847(b)(2)(A)(iii) of the Act, that CMS would not award a contract under the DMEPOS CBP if CMS determines the total amount paid under the DMEPOS CBP would be greater than all payments that would otherwise be made—inclusive of payments made pursuant to improper billing and any other expenses paid under the DMEPOS fee schedules. Accompanying this proposal, we propose to modify under what circumstances CMS would not award a contract for a competition under 42 CFR 414.414(f) and modify the maximum bid amounts allowed for bids under 42 CFR 414.412.

We are soliciting comments on these proposals.

1. Background

Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts to any entity unless the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid under the methodologies set forth in sections 1834 and 1842 of the Act. We emphasize that the language in the statute refers to “total amounts paid” and not to individual payment amounts. Other factors other than the specific dollar amount paid per item can impact the total amounts paid.

In the 2007 final rule (72 FR 18084) CMS implemented the DMEPOS CBP and established that bids submitted for each item in a product category could not exceed the payment that would otherwise be made under the existing fee schedule methodology (42 CFR 414.412(b)(2)). We stated that we would not accept any bid for an item that is higher than the current fee schedule amount for that item. This approach would ensure that the SPA for each item in a product category is equal to or less than our current fee schedule amount for that item. As noted in the rule, we implemented this policy in part out of concern that if contracts were awarded that allowed higher prices for some items while lower prices for others, this could incentivize improperly shifting utilization to the higher-priced items, defeating the intent that the CBP create savings.

Section 1834(a)(1)(F)(ii) and (iii) of the Act requires the Secretary to use information on the payment determined under a DMEPOS competitive bidding program to adjust the DMEPOS fee schedule amounts in areas where competitive bidding is not in effect. Authority for adjusting payment amounts in a similar manner for OTS orthotics, lymphedema compression treatment items, and enteral nutrition is provided by sections 1834(h)(1)(H)(ii), 1834(z)(3)(B), and 1842(s)(3)(B) of the Act, respectively. In the final rule implementing these provisions, published in the **Federal Register** on November 6, 2014, and titled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies”, we noted that these adjusted fee schedule amounts would serve as the bid limit for future competitive bidding (79 FR 66120).

In the November 2016 final rule, we established an alternative “lead item” bidding method for submitting bids and determining SPAs for certain groupings of similar items (for example, walkers)

with different features (wheels, folding, etc.) under the DMEPOS CBP. (81 FR 77834). To conform with this change, the bid limit language at 42 CFR 414.412(b)(2) was updated to refer to “lead items.” Along with this change, the rule also changed the bid limit from the adjusted fee schedule amount to the unadjusted fee schedule amount. As the preamble to the rule noted, this change to bid limits was made to address concerns that use of adjusted fees as the bid limit may make the DMEPOS CBP unviable as cost pressures evolve over time (81 FR 77950).

2. Current Issues

As discussed previously, CMS announced that it would not award competitive bidding contracts for 13 product categories for Round 2021 that were previously competed because the payment amounts did not achieve expected savings. In addition to the changes proposed elsewhere in this rule, we believe that further changes to the bid limit provisions at § 414.412(b)(2) and conditions for awarding contracts at § 414.414(f) are needed to ensure both the continued viability of the DMEPOS CBP and adherence to the requirement for savings laid out in 1847(b)(2)(A)(iii) of the Act. We also believe that differing approaches to bid limits are needed for items that have been included in a previous round of competitive bidding and those that have not because the specific amounts that would otherwise be paid for the former are adjusted based on rates established under previous rounds of the DMEPOS CBP while the specific amounts that would otherwise be paid for the later have not yet been adjusted based on rates established under the DMEPOS CBP.

The expectation of savings has been at the heart of the DMEPOS CBP since its inception for good reason. In examining the first two rounds of bidding, the GAO found that among the products that had been part of the Round 1 Rebid, the Round 1 Recompete, and Round 2, the SPA continued to decrease with each competition for all products except for standard power wheelchairs (which decreased with the first round and remained below the pre CBP payment amount in subsequent rounds). The largest price decrease occurred with the initial round of bidding, with savings ranging from 20 to 50 percent as compared to the previous Medicare fee schedule payment amounts (<https://www.gao.gov/assets/gao-15-63.pdf>). With the Round 2 expansion of the program, SPAs were, on average, 45 percent less than the fee schedule amounts, and SPAs for the national mail

order program for diabetes supplies were, on average, 72 percent less than the previous fee schedule amounts.

However, as explained in section VII.A.1., in addition to the price savings, there are two important benefits of the DMEPOS CBP that must be taken into consideration: guaranteed access for beneficiaries and reductions in improper utilization. Outside of the DMEPOS CBP, Medicare functions as an open network. Suppliers may choose which items to provide, and there is understandable market pressure to focus on more profitable or higher-volume items. Also, despite successful efforts to target waste, fraud, and abuse, it is often difficult to identify bad actors until claims patterns have demonstrated areas of concern. Within the DMEPOS CBP, instances of waste, fraud, and abuse are less likely to occur for two reasons: lower payment amounts reduce the profit to be made from improper payments, and the reduction in number of suppliers and heightened scrutiny and monitoring of contract suppliers makes it more difficult for entities, particularly new entrants, intending to commit fraud to gain access to the program.

While it is difficult to put a dollar amount on the benefit of guaranteed access for beneficiaries, it is possible to quantify the impact the DMEPOS CBP has had on reducing improper utilization. In its study of the DMEPOS CBP Round 1 Rebid, the GAO found that the number of beneficiaries furnished DME items covered by the CBP decreased more in the competitive bidding areas than in non-competitive bidding areas (<https://www.gao.gov/assets/gao-14-156.pdf>), even as monitoring of medical outcomes and beneficiary complaints did not suggest any difficulties in beneficiary access. Although the specific decrease in utilization varied across product categories, this study found decreases of 10 to 20 percent attributable to the CBP. The GAO study of Round 2 found a 17 percent decrease in the number of beneficiaries receiving items covered by the DMEPOS CBP as compared to 6 percent in non-CBP areas (in the context of a broader enforcement program that saw over 580,000 providers lose billing privileges). Similarly to Round 1, this decrease was not accompanied by any evidence that beneficiaries were unable to access needed equipment, and the competitive bidding areas experiencing the largest decreases in utilization were in states with historically high rates of fraud and abuse (<https://www.gao.gov/assets/gao-16-570.pdf>).

Given these findings, it is clear that the historic savings generated by the

DMEPOS CBP come from two sources: the reduction in price that comes from the competitive bidding process and a reduction in improper utilization.

Because the evidence suggests a 10 to 20 percent reduction in waste, fraud, and abuse is associated with the DMEPOS CBP, we believe that it is appropriate and consistent with 1847(b)(2)(A)(iii) of the Act to award contracts in a CBA even if the SPA is 10 percent higher than the adjusted fee schedule payment amount that would otherwise be paid for items included under previous rounds of the DMEPOS CBP, as long as the SPA does not exceed the unadjusted fee schedule amounts for the items and services or the fee schedule amounts in effect prior to the application of the fee schedule adjustments using the methodologies under 42 CFR 414.210(g).

(a) Limits on SPAs

We are soliciting comments on a proposal to modify 42 CFR 414.414(f) to specify that a contract would not be awarded for a competition if the SPA for the lead item would be greater than the lesser of 110 percent of the adjusted fee schedule amount for the lead item, if applicable, or 100 percent of the unadjusted fee schedule amount for the lead item. This proposal is different than the bid limit proposal discussed under “(b) Submissions of bids” because the fee schedule amounts for items and services included under previous rounds of the DMEPOS CBP are adjusted using SPA data from multiple CBAs in different regions of the nation, and in the case of the adjusted fee schedule amounts for items furnished in rural and non-contiguous areas, the adjusted fee schedule amounts include a 50 percent blend of the unadjusted fee schedule rates. As a result, the amount that would otherwise be paid in a CBA at the adjusted fee schedule rates using SPA pricing from multiple CBAs and in some cases updated, unadjusted fee schedule rates could be higher than the previous SPAs established in the specific CBA.

(b) Submission of Bids

For similar reasons, we are soliciting comments on a proposal for several modifications to 42 CFR 414.412 regarding the bid amounts submitted for competitions under a DMEPOS CBP to better ensure that total payments to contract suppliers would be no higher than the total payments that would otherwise be made for the items and services in the CBA.

We are also soliciting comments on a proposal to modify 42 CFR 414.412(b)(2) to expressly specify that the bid submitted for each lead item and

product category included under the DMEPOS CBP for the first time must not exceed the unadjusted fee schedule amount for the lead item.

For items included in a prior competition, we are soliciting comments on a proposal to modify 42 CFR 414.412(b) to require that the bid submitted for each lead item and product category must not exceed, for the same CBA, the lesser of the most recent SPA for the item plus 10 percent or the unadjusted fee schedule amount for the item. If it has been more than one year since the most recent SPA was last paid due to a temporary gap in the CBP, we are proposing that the bid for the lead item must not exceed the lesser of the most recent SPA for the item, adjusted by an inflation factor, plus 10 percent or the unadjusted fee schedule amount for the item. Updating the most recent SPA in this manner allows for the bid limit to address the possible effects of inflation since last paid. We are also soliciting comments on a proposal that the inflation adjustment factor would be based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) from the mid-point of the 12-month period that the most recent SPA was in effect to the date that is 6 months prior to the date CMS announces the dates suppliers may register and submit bids under the applicable round of competition.

We are soliciting comments on a proposal that the bid submitted for each lead item and product category included in a prior competition but made under a bid for a new CBA must not exceed the lesser of the adjusted fee schedule amount for the lead item plus 10 percent or the unadjusted fee schedule amount for the lead item. For the same reasons noted previously for adding 10 percent to the SPA for the lead item from a previous competition in the same CBA, we are proposing to add 10 percent to the adjusted fee schedule amount for the lead item in this case since the adjusted fee schedule amounts are the amounts that would otherwise be paid and are based on SPAs from previous competitions.

Bidding entities would be educated that they would not be allowed to enter bids that are higher than these proposed limits. The SPAs going from one round to the next would not be able to exceed the 10 percent increase in payments that, as discussed previously, we believe would still allow contracts to be awarded in accordance with section 1847(b)(2)(A)(iii) of the Act.

As discussed in section VII.F.3., OTS back braces and OTS knee braces are currently delivered to beneficiaries from remote supplier locations that on

average are hundreds of miles from the beneficiary's residence. We are therefore soliciting comments on a proposal to establish a nationwide or regional CBA(s) for items such as OTS back braces and OTS knee braces to be phased in at some point in the future. We are soliciting comments on a proposal to amend 42 CFR 414.412(b) to establish bid limits for OTS back braces and OTS knee braces for the first time they are phased in as the lead item in a product category under a nationwide or regional CBA(s). OTS back braces and OTS knee braces were included under the DMEPOS CBP in over 100 CBAs from 2021 through 2023 with SPAs calculated using maximum winning bid amounts. The fee schedule amounts for OTS back braces and OTS knee braces are adjusted based on the prices established under this round of the DMEPOS CBP. In accordance with regulations at 42 CFR 414.210(g)(1), the fee schedule amounts for nonrural areas within the contiguous United States are adjusted based on regional average SPAs limited by a national ceiling and floor. The average of the 2025 fee schedule amounts for nonrural areas for HCPCS level II code L0450 for example is \$124.53. By comparison, the average of the 2025 adjusted fee schedule amounts for these items when furnished to beneficiaries in rural areas within the contiguous United States and areas outside the contiguous United States for HCPCS level II code L0450 is \$184.76. The higher fee schedule amounts established for these areas in accordance with regulations at 42 CFR 414.210(g)(2)(ii) and (iii) account for higher costs of suppliers furnishing items in these areas. However, these items are being furnished mostly by mail to beneficiaries across the nation from remote supplier locations. The cost of shipping an item from a remote location to a beneficiary residing in a rural area is typically no higher than the cost of shipping an item from a remote location to a beneficiary residing in a nonrural area. Additional shipping and handling costs may be incurred in some cases for items that are shipped to an area outside the contiguous United States such as Alaska, Hawaii, or Puerto Rico, but there are very few beneficiaries living in these areas compared to areas within the contiguous United States. We are soliciting comments on a proposal that the bids submitted for an OTS back brace or an OTS knee brace included as a lead item in a product category in a nationwide or regional RID CBP for the first time cannot exceed the average of the nonrural fee schedule amounts that

would otherwise apply to the item under subpart D of this part for the areas included in the nationwide or regional CBP.

While we believe this bid limit for items that have previously been part of competitive bidding is important in terms of balancing the benefits of the DMEPOS CBP with the statutory requirement for savings, we also recognize that it may be possible in the long term that the bid limit as previously described may, in fact, exceed the unadjusted fee schedule amounts for certain items. For this reason, we propose a "fail-safe" to ensure that the bid limit would never exceed the unadjusted fee schedule amount.

3. Provisions of the Proposed Regulation

We are proposing to amend 42 CFR 414.412 to amend paragraph (b)(2) to specify that this paragraph would apply to items included under the DMEPOS CBP for the first time, and to streamline the text by deleting the references to the application of §§ 414.210(g), 414.105, and 414.1690. We are proposing to renumber paragraphs (b)(3) through (b)(5) as (b)(6) through (b)(8), respectively. We are proposing to add a new paragraph (b)(3) to set the bid limit for items that have been previously included under a competition for the same CBA with a SPA used to pay contract suppliers as the lesser of the most recent SPA plus 10 percent or the unadjusted fee schedule amount for the item. We are proposing to add a new paragraph (b)(4) to specify that if it has been more than one year since the most recent SPA was last paid, the amount under (b)(3) would be adjusted by the percentage change in the CPI-U from the mid-point of the 12-month period the most recent SPA was in effect to the date that is 6 months prior to the date CMS announces the dates suppliers may register and submit bids under the current round of competition. Should either the most recent SPA plus 10 percent or the most recent SPA plus 10 percent and the increases for inflation for SPAs that have not been used for payment for more than one year exceed the unadjusted fee schedule amount for the lead item, the bid submitted would be limited to the unadjusted fee schedule amount. We are proposing to add new paragraph (b)(5) to set the bid limit for items that have been previously included under the DMEPOS CBP but are being phased into a CBA where the items have never been bid as the adjusted fee schedule amount for the lead item plus 10 percent. If the adjusted fee schedule amount for the lead item plus 10 percent exceeds the

unadjusted fee schedule amount for the lead item, the bid submitted would be limited to the unadjusted fee schedule amount for the lead item. We are proposing to specify under new paragraph (b)(9) that the bid amounts submitted for rental of class II continuous glucose monitors included as a lead item in a product category in a RID CBP for the first time must not exceed the payment amount that would otherwise apply to the monthly fee schedule amount for the supplies for the class II continuous glucose monitor under subpart D of this part plus the average of the purchase fee schedule amounts that would otherwise apply to the class II continuous glucose monitor for the areas included in the RID CBP divided by 60. We are proposing to specify under new paragraph (b)(10) that the bid amounts submitted for rental of insulin infusion pumps included as a lead item in a product category in a RID CBP for the first time must not exceed the nonrural adjusted fee schedule amount that would otherwise apply to the supplies and accessories for the insulin infusion pump under subpart D of this part for a 1-month period plus the total nonrural adjusted rental fee schedule amounts that would otherwise apply to the rental of the insulin pump for 13 months of continuous use under subpart D of this part divided by 60. We are proposing to specify under new paragraph (b)(11) that the bid amounts submitted for an OTS back brace or OTS knee brace included as a lead item in a product category in a RID CBP for the first time cannot exceed the average nonrural payment amount that would otherwise apply to the item under subpart D of this part, with the application of § 414.210(g), for the areas included in the RID CBP. We are proposing to specify under new paragraph (b)(12) that the bid amounts submitted for all other items included as a lead item in a product category in a RID CBP for the first time must not exceed the average payment amount that would otherwise apply to the item under subpart C, D, or Q of this part for the areas included in the RID CBP.

We are proposing to amend 42 CFR 414.414(f) to state that contracts cannot be awarded for a competition unless CMS determines the SPA to be paid to contract suppliers for the lead item would be no greater than the lesser of 110 percent of the adjusted fee schedule amount for the item, if applicable, or the unadjusted fee schedule amount for the lead item.

We are soliciting comments on these proposals.

E. Revising the Definition of “Item” Related to Medical Supplies

Section 1847(a)(1) of the Act requires that the Secretary phase in all included items and services for competitive bidding. Including items in competitive bidding generates savings for Medicare Part B. Certain items may present a particular risk for improper utilization, and prioritizing these items for competitive bidding may facilitate a reduction in improper utilizations. For these reasons, we are proposing to facilitate the statutorily mandated expansion of the competitive bidding program by clarifying the definition of “medical equipment items”, to include ostomy, tracheostomy, and urological supplies.

1. Background

Section 1847(a)(1)(B) of the Act authorizes the Secretary to phase in CBPs first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

In the 2007 final rule we stated we would rely on several variables in determining the savings potential for specific items or categories of items. Those variables include annual allowed charges, annual growth in expenditures, number of suppliers, savings under the demonstrations, and various reports and studies conducted by CMS and other Federal agencies (72 FR 18025).

We received several comments in the 2007 final rule from commenters who believed that ostomy products and supplies do not meet the definition of DME and, therefore, are not part of the items and services subject to the CBPs described in section 1847(a)(2)(A) of the Act (72 FR 18023). We responded that we believe that section 1847(a)(2)(A) of the Act is ambiguous regarding whether ostomy products and supplies are to be included in the Medicare DMEPOS CBP because the term “medical supplies” in the section heading could be interpreted either to modify the term “durable medical equipment” (meaning that the medical supplies would have to be associated with the DME to be included), or to be a separate category of items that are not associated with DME. In addition, although the definition of “covered item” in section 1834(a)(13) of the Act means “durable medical equipment (as defined in section 1861(n) [of the Act]), including such equipment described in section 1861(m)(5) [of the Act] . . .,” the term “such equipment” in section 1861(m)(5) of the Act could be interpreted to refer either to the term “durable medical

equipment” or to the term “medical supplies” (which would include ostomy supplies) in that section. In light of these ambiguities, we stated that we believe we have discretion to interpret section 1847(a)(2)(A) of the Act to include or exclude ostomy products and supplies in the competitive bidding programs. We did not exercise our authority to include these items at that time and stated we would continue to review this issue.

Prior to enactment of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Public Law 108–173; section 4319 of the Balanced Budget Act of 1997 (BBA), Public Law 105–33, authorized implementation of up to five demonstration projects of competitive bidding for Medicare Part B items, except physician services. In accordance with section 4319 of the BBA, we planned and implemented the DMEPOS Competitive Bidding Demonstration to test the feasibility and program impacts of using competitive bidding to set prices for DMEPOS. The demonstration was implemented at two sites: Polk County, Florida, and in the San Antonio, Texas, Metropolitan Statistical Area (MSA). The competitive bidding demonstrations, authorized under the BBA, were implemented successfully in both demonstration sites from 1999 to 2002, resulted in a substantial savings to the program, and offered beneficiaries sufficient access and quality products.

At the first site, Polk County, Florida, we conducted the first of two rounds of bidding in 1999. Five categories of DMEPOS were put up for bidding: oxygen equipment and supplies (required by statute); hospital beds and accessories; enteral nutrition formulas and equipment; urological supplies; and surgical dressings. A total of 16 contract suppliers began providing demonstration products in Polk County on October 1, 1999, and continued for 2 years. The second and final round of bidding in Polk County was conducted in 2001 for the same product categories minus enteral nutrition (Enteral nutrition was dropped to retain only product categories that are overwhelmingly used in private homes). The second set of competitively bid payment amounts took effect in October 2001. As in round one, 16 suppliers were selected, of whom half had participated as winners previously. The new fee schedules developed from the bids in each round replaced the Statewide Medicare DMEPOS fees. The second round of the demonstration in Polk County ended in September 2002. Texas was the second site for the demonstration. In Bexar, Comal, and

Guadalupe counties in the San Antonio MSA, we conducted bidding in 2000 for five kinds of DMEPOS: oxygen equipment and supplies; hospital beds and accessories; wheelchairs and accessories; general orthotics; and nebulizer drugs. Fifty-one suppliers were selected and began serving Medicare beneficiaries under the new fees in February 2001. The San Antonio site ended operations in December 2002, the statutorily required termination date in the BBA.

In each area of evaluation, the data indicated mostly favorable results for the Medicare program. The demonstration led to lower Medicare fees for almost every item in almost every product category in each round of bidding. Fee reductions varied by product category and item, resulting in a nearly 20 percent overall savings at each site. Statistical and qualitative data indicate that beneficiary access and quality of services were essentially unchanged. For urological supplies, the estimated savings rate for the first round of the demonstration in Polk County were \$16,409, which were 18 percent, and Round 2 bidding in Polk County resulted in 9 percent savings (72 FR 18078). Our findings from beneficiary surveys in Polk County did not indicate that beneficiaries using urological supplies experienced any negative impact on the quality of their equipment.⁸⁰

Multiple winners were selected in each product category in each round of bidding. In Polk County, non-demonstration suppliers in Round 1 bid successfully in Round 2. However, the falling number of bidders for urological supplies raised questions about the feasibility of bidding for products with low allowed charges. At the time, this product category did not have a single dominant product code, with the items with the highest allowed charges accounting for only 28 percent of total Medicare allowed charges for urological supplies.

2. Current Issues

There have been several reports detailing Medicare’s excessive payment rates for items not included in the DMEPOS CBP. In 2018, the Medicare Payment Advisory Commission (MedPAC) released a report describing how Medicare expenditures for DMEPOS products excluded from the CBP have continued to grow.⁸¹ MedPAC discussed how “. . . some non-CBP

⁸⁰ <https://www.cms.gov/files/document/2rtcappendixpdf>.

⁸¹ https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_ch6_medpacreport_sec.pdf.

DMEPOS products continue to generate high rates of improper payments, experience high utilization growth, and exhibit patterns of potential fraud and abuse.” In this report, MedPAC looked at ostomy, tracheostomy, and urological supplies (for example, catheters), and found two products for which Medicare’s payment rates were 45 percent and 57 percent higher than private-payer rates. Specifically, intermittent urinary curved tip catheters under HCPCS Level II code A4352 were 57 percent more, whereby Medicare could save \$37 million dollars if Medicare paid the median private-payer rate. Intermittent urinary straight tip catheters (HCPCS Level II code A4351) were 45 percent more, whereby Medicare could save \$41 million dollars if Medicare paid the median private-payer rate.

In August 2022, the HHS Office of Inspector General (OIG) released a report titled, “Reducing Medicare’s Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year” (OEI-04–20–00620).⁸² The report found that, “Medicare and its beneficiaries paid suppliers \$407 million for intermittent urinary catheters in fiscal year 2020, more than three times the suppliers’ estimated acquisition costs of \$121 million.” Based on these findings, OIG recommended that CMS lower Medicare’s payment rates for intermittent urinary catheters. OIG noted that CMS could incorporate such items into the DMEPOS CBP.

We have also seen significant growth in allowed charges for ostomy, tracheostomy, and urological supplies. In 2001, the second year of the demonstration in Polk County, total allowed charges for intermittent urinary curved tip catheter HCPCS Level II code A4352 were \$1,779,928 while total allowed charges for intermittent urinary straight tip catheters HCPCS Level II code A4351 were \$5,753,184. Total allowed charges have increased significantly for these items in 2022, to \$344,012,449 for HCPCS Level II code A4352 and \$153,606,517 for HCPCS Level II code A4351. Medicare allowed charges for ostomy supplies have also grown significantly. For instance, total allowed charges for HCPCS Level II code A4407 for ostomy skin barriers increased from \$12,990,011 in 2003 to \$37,478,467 in 2022. Additionally, prior reviews performed by OIG and CMS contractors have identified high improper payment rates for urological

supplies (including intermittent urinary catheters) that did not meet Medicare requirements.⁸³ We also published in the **Federal Register** on September 27, 2024 a Medicare Shared Savings Program final rule (89 FR 79152), in which we discussed significant, anomalous, and highly suspect (SAHS) billing activity for certain intermittent urinary catheters on Medicare DMEPOS claims in CY 2023. We finalized several proposals as a result of this SAHS billing activity, one of which was to specify in the Shared Savings Program regulations at § 425.670(b) that CMS has determined that the billing of HCPCS codes A4352 (Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each) and A4353 (Intermittent urinary catheter, with insertion supplies) represents SAHS billing activity for CY 2023 that would have caused significantly inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if not addressed (89 FR 79158).

Further information about this urinary catheter fraud that CMS identified in 2023 can be found in a CMS case study titled “Urinary Catheter Case Study: CMS’ Swift Action Saves Billions”.⁸⁴ In sum, CMS identified a concerning rise in urinary catheter billings attributed to a small group of 15 DMEPOS supply companies that had recently changed ownership. Through investigative work, CMS determined that people with Medicare did not receive catheters from these DMEPOS companies and were not billed directly, physicians did not order these supplies, and the supplies were not needed. While CMS took swift action to protect people with Medicare and the Medicare program in this situation,⁸⁵ including ostomy, tracheostomy, and urological supplies in the DMEPOS CBP may mitigate such situations in the future.

⁸³ <https://oig.hhs.gov/documents/audit/10169/A-09-22-03019.pdf>.

⁸⁴ <https://www.cms.gov/files/document/cpi-urinary-catheter-case-study.pdf>.

⁸⁵ Using fraud prevention tools, CMS stopped over 99% of the payments to the small group of potential bad actors before they went out the door. There was no impact to legitimate suppliers providing medically necessary services to people with Medicare. CMS revoked enrollment of the 15 potential bad actors from Medicare between late 2023 and 2024, meaning they are no longer able to bill Medicare for services and cannot re-enroll for up to 10 years. CMS also replaced hundreds of thousands of Medicare Beneficiary Identifiers (MBIs) that were used to file the suspicious claims, changed the MBI of the most at-risk people with Medicare, and completed changing all impacted MBI in March 2024.

3. Provisions of the Proposed Regulation

We are soliciting comments on our proposal that the medical equipment set forth at section 1861(m)(5) of the Act, namely home health medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and certain covered osteoporosis drugs) be included in the list of items CMS may subject to the DMEPOS CBP. In general, section 1847(a)(1)(A) of the Act states the Secretary must establish and implement competitive bidding for covered items. In identifying the scope of covered items subject to the DMEPOS CBP, section 1847(a)(2) of the Act relies on section 1834(a)(13) of the Act, which defines covered items as durable medical equipment, as defined at section 1861(n) of the Act (including supplies used in conjunction with durable medical equipment), and certain equipment described in section 1861(m)(5) of the Act used to furnish home health services, such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and certain covered osteoporosis drugs. Consequently, we believe that ostomy, tracheostomy, and urological supplies are included within the scope of section 1847(a)(2)(A) of the Act that CMS may select for competitive bidding. We no longer believe that section 1847(a)(2)(A) of the Act is ambiguous regarding whether ostomy products and supplies are to be included in the Medicare DMEPOS CBP.

Additionally, the Conference Report for the MMA of 2003 (H. Rept. 108–391) says, “The Secretary would be required to establish and implement competitive acquisition programs for durable medical equipment, medical supplies, items used in infusion, drugs and supplies used in conjunction with durable medical equipment, medical supplies, home dialysis supplies, blood products, parental nutrition, and off the-shelf orthotics (requiring minimal self-adjustment for appropriate use) that would replace the Medicare fee schedule payments.”⁸⁶ Here, the second mention of “medical supplies” is a distinct category from “durable medical equipment” and from “drugs and supplies used in conjunction with durable medical equipment”.

We are soliciting comments on a proposal to add equipment described in section 1861(m)(5) of the Act, including ostomy, tracheostomy, and urological supplies to the definition of “Item” under § 414.402(6). We are also soliciting comments on a proposal to

⁸² <https://oig.hhs.gov/oei/reports/OEI-04-20-00620.pdf>.

⁸⁶ <https://www.congress.gov/108/crpt/hrpt391/CRPT-108hrpt391.pdf>.

add § 414.408(g)(6) to specify medical equipment, including ostomy, tracheostomy, and urological supplies are purchased items for which the SPA is calculated based on the bids submitted and accepted.

F. Remote Item Delivery (RID) CBP

We are soliciting comments on a proposal to establish definitions for “remote item delivery CBP” and “remote item delivery item.” A remote item delivery CBP is similar to a mail order CBP except that items furnished on a non-mail basis would not be excluded from the remote item delivery CBP as they are under a mail order CBP.

1. Background

In a September 2004 report (GAO–04–765), GAO recommended that we consider using mail delivery for items that can be provided directly to beneficiaries in the home as a way to implement a DMEPOS competitive bidding strategy. The report stated that “Because MMA authorizes CMS to designate the geographic areas for competition for different items, designating the entire country as the competitive area for selected items is a possibility.” The GAO noted that demonstration suppliers provided surgical dressings, urological supplies, and inhalation drugs to beneficiaries by mail.⁸⁷ Additionally, the GAO noted that the MMA states that areas within MSAs that have low population density should not be excluded from competition if a significant national market exists through mail order for a particular item or service. The GAO went on to say that “in contrast to conducting competitive bidding on a piecemeal basis in multiple geographic areas, a consolidated nationwide approach would allow CMS to more quickly implement competitive bidding on a large scale.” The GAO also stated that “this approach would enable companies that provide, or demonstrate the ability to provide, nationwide mail order service to compete for Medicare beneficiaries’ business.” In the report we stated that CMS would explore the feasibility of GAO’s recommendation to consider using mail-order delivery for items that could be provided directly to beneficiaries in the home, as a way to

implement a national competitive bidding strategy.

In response, we have continued to review and evaluate avenues to expand mail delivery for items under the DMEPOS CBP. In the 2006 proposed rule (71 FR 25669), we stated that our data shows that a significant percentage of certain items such as diabetes testing supplies (blood glucose test strips and lancets) are furnished to beneficiaries by national mail order supplier and proposed to establish a nationwide or regional competitive bidding program, effective for items furnished on or after January 1, 2010, for the purpose of awarding contracts to suppliers to furnish these items across the nation or region to beneficiaries who elect to obtain them through the mail order outlet. Specifically, we proposed in § 414.410(d)(2) and § 414.412(f) and (g) to establish a nationwide competitive bidding program or regional competitive bidding programs for the purpose of awarding contracts to suppliers to furnish these items across the nation or region to beneficiaries who elect to obtain them through the mail. We proposed that the national or regional CBAs under the Medicare DMEPOS CBP would be phased in after CY 2009, and payment would be based on the bids submitted and accepted for the furnishing of items through mail order throughout the nation or region. Suppliers that furnish these items through mail order on either a national or regional basis would be required to submit bids to participate in any CBP implemented for the furnishing of mail order items.

In the 2007 final rule (72 FR 18018), we finalized these proposals and specified that our data indicated that over 60 percent of Medicare expenditures for diabetes supplies are for items furnished by nationwide mail order suppliers. In the 2007 final rule (72 FR 18018), we stated that any national or regional mail order CBP that we might choose to implement starting in CY 2010 would be limited to the furnishing of items “through the mail.” The 2007 final rule included the addition of definitions under § 414.402 related to nationwide or regional CBPs.

A national mail order CBP was implemented for diabetes testing supplies (supplies for blood glucose monitors) from July 1, 2013, through

December 31, 2018. Prior to implementing this national mail order program, as part of a final rule published in the **Federal Register** on November 29, 2010, titled “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011” (75 FR 73567), we established definitions for “mail order item” and “non-mail order item” in § 414.402. These definitions were established to clarify that a mail order item is not limited to an item that is literally furnished through the mail (United States Postal Service) and includes any item delivered to the beneficiary, whereas a non-mail order item was an item the beneficiary picked up in person at a local pharmacy or other supplier storefront. The definition for “mail order item” is “any item (for example, diabetes testing supplies) shipped or delivered to the beneficiary’s home, regardless of the method of delivery.” The definition for “non-mail order item” is “any item (for example, diabetes testing supplies) that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront.” Non-mail order diabetes testing supplies were not included under the national mail order program. However, the fee schedule amounts for these items are established based on the payment amounts determined for the items under the national mail order program in accordance with section 1834(a)(H) of the Act.

2. Current Issues

Medicare claims data shows that several high-volume categories of items subject to the DMEPOS CBP are furnished to beneficiaries throughout the nation from remote supplier locations. As shown in table 45, the national average distance between the beneficiary address and supplier location is several hundred miles for the lead items in seven, high volume categories of items. The average delivery distance was measured based on the distance between the beneficiary residence and supplier location for all claims with dates of service in calendar year 2024 for the “lead item” in the category of items, or the item with the highest total nationwide Medicare allowed charges in 2024 of any item in the category.

⁸⁷ <https://www.gao.gov/assets/gao-04-765.pdf>.

TABLE 45: CATEGORIES OF ITEMS FURNISHED FROM REMOTE SUPPLIER LOCATIONS

Category	2024 Allowed Charges for the Category	Lead Item	Average Distance ⁸⁸ (Lead Item)
Class II Continuous Glucose Monitors	\$1.945 million	A4239	813 miles
Urological Supplies ¹	\$1,214 million	A4353	784 miles
Ostomy Supplies ¹	\$436 million	A5057	758 miles
Insulin Pumps	\$151 million	E0784	679 miles
Off-the-shelf Knee Braces	\$138 million	L1852	1047 miles
Off-the-shelf Upper Extremity Braces	\$127 million	L3916	1049 miles
Off-the-shelf Back Braces	\$126 million	L0651	976 miles

¹ Urological supplies and ostomy supplies categories have 9 overlapping HCPCS codes at \$16 million

We are soliciting comments on a proposal that items like those listed in Table 45 that are generally furnished from remote supplier locations should be included under a remote item delivery CBP that does not exclude non-mail order items as is the case under a mail order CBP.

Rather than implementing hundreds of local CBPs and CBAs and placing unnecessary burden on the bidding program and suppliers, we believe the easiest and best way to implement CBPs for remotely delivered items such as these is to include them under product

categories in one nationwide “RID” CBP or several large regional “RID” CBPs, which would consist of all areas where a beneficiary resides or receives covered items under the product categories, with limited exceptions as explained later in this section. This is consistent with the findings of a report from the GAO from September 2004⁸⁹ that discussed the use of national CBAs as a way to streamline the implementation of the CBP. Listed in table 46 are the current HCPCS Level II codes for several product categories we believe should be

included under a future RID CBP(s) because they are typically furnished to beneficiaries from remote supplier locations, or locations that are hundreds of miles on average from the beneficiary residence where the items are delivered. This table is for illustration purposes only. The actual product categories to be phased in under a RID CBP(s) would be designated through program instructions or by other means in accordance with existing regulations at § 414.406(d).

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⁸⁹ <https://www.gao.gov/assets/gao-04-765.pdf>.

TABLE 46: EXAMPLES OF RID CBP PRODUCT CATEGORIES AND HCPCS CODES

Product Category	HCPCS Level II Code	Short Description
Class II CGMs and Insulin Pumps	A4224	Supply insulin inf cath/wk
Class II CGMs and Insulin Pumps	A4225	Sup/ext insulin inf pump syr
Class II CGMs and Insulin Pumps	A4239	Non-adju cgm supply allow
Class II CGMs and Insulin Pumps	E0784	Ext amb infusn pump insulin
Class II CGMs and Insulin Pumps	E2103	Non-adju cgm receiver/mon
OTS Back Brace	L0450	Tlso flex trunk/thor pre ots
OTS Back Brace	L0455	Tlso flex trnk sj-t9 pre ots
OTS Back Brace	L0457	Tlso flex trnk sj-ss pre ots
OTS Back Brace	L0467	Tlso r fram soft pre ots
OTS Back Brace	L0469	Tlso rig fram pelvic pre ots
OTS Back Brace	L0621	Sio flex pelvic/sacr pre ots
OTS Back Brace	L0623	Sio rig pnl pelv/sac pre ots
OTS Back Brace	L0625	Lo flex l1-below l5 pre ots
OTS Back Brace	L0628	Lso flex no ri stays pre ots
OTS Back Brace	L0641	Lo rig pos pnl l1-l5 pre ots
OTS Back Brace	L0642	Lo sag ri an/pos pnl pre ots
OTS Back Brace	L0643	Lso sag ctr rigi pos pre ots
OTS Back Brace	L0648	Lso sag r an/pos pnl pre ots
OTS Back Brace	L0649	Lso sc r pos/lat pnl pre ots
OTS Back Brace	L0650	Lso sc r ant/pos pnl pre ots
OTS Back Brace	L0651	Lso sag-co shell pnl pre ots
OTS Knee Brace	L1812	Ko elastic w/joints pre ots
OTS Knee Brace	L1830	Ko immob canvas long pre ots
OTS Knee Brace	L1833	Ko adj jnt pos r sup pre ots
OTS Knee Brace	L1836	Ko rigid w/o joints pre ots
OTS Knee Brace	L1850	Ko swedish type pre ots
OTS Knee Brace	L1851	Ko single upright prefab ots
OTS Knee Brace	L1852	Ko double upright prefab ots
OTS Upper Extremity Brace	L3650	So 8 abd restraint pre ots
OTS Upper Extremity Brace	L3660	So 8 ab restr can/web pre ots
OTS Upper Extremity Brace	L3670	So acro/clav can web pre ots
OTS Upper Extremity Brace	L3675	So vest canvas/web pre ots
OTS Upper Extremity Brace	L3678	So hard plas stabili pre ots
OTS Upper Extremity Brace	L3710	Eo elas w/ metal jnts pre ots
OTS Upper Extremity Brace	L3761	Eo, adj lock joint prefab ot
OTS Upper Extremity Brace	L3762	Eo rigid w/o joints pre ots
OTS Upper Extremity Brace	L3809	Whfo w/o joints pre ots
OTS Upper Extremity Brace	L3908	Who cock-up nonmolde pre ots
OTS Upper Extremity Brace	L3912	Hfo flexion glove pre ots
OTS Upper Extremity Brace	L3916	Who nontorsion jnts pre ots
OTS Upper Extremity Brace	L3918	Metacarp fx orthosis pre ots
OTS Upper Extremity Brace	L3924	lifo without joints pre ots
OTS Upper Extremity Brace	L3925	Fo pip dip jnt/springs pre ots
OTS Upper Extremity Brace	L3927	Fo pip dip no jt spr pre ots
OTS Upper Extremity Brace	L3930	Hfo nontorsion jnts pre ots
Ostomy Supplies	A4331*	Extension drainage tubing
Ostomy Supplies	A4357*	Bedside drainage bag

Product Category	HCPCS Level II Code	Short Description
Ostomy Supplies	A4361	Ostomy face plate
Ostomy Supplies	A4362	Solid skin barrier
Ostomy Supplies	A4363	Ostomy clamp, replacement
Ostomy Supplies	A4364	Adhesive, liquid or equal
Ostomy Supplies	A4366	Ostomy vent
Ostomy Supplies	A4367	Ostomy belt
Ostomy Supplies	A4368	Ostomy filter
Ostomy Supplies	A4369	Skin barrier liquid per oz
Ostomy Supplies	A4371	Skin barrier powder per oz
Ostomy Supplies	A4372	Skin barrier solid 4x4 equiv
Ostomy Supplies	A4373	Skin barrier with flange
Ostomy Supplies	A4375	Drainable plastic pch w fcpl
Ostomy Supplies	A4376	Drainable rubber pch w fcplt
Ostomy Supplies	A4377	Drainable plstic pch w/o fp
Ostomy Supplies	A4378	Drainable rubber pch w/o fp
Ostomy Supplies	A4379	Urinary plastic pouch w fcpl
Ostomy Supplies	A4380	Urinary rubber pouch w fcplt
Ostomy Supplies	A4381	Urinary plastic pouch w/o fp
Ostomy Supplies	A4382	Urinary hvy plstc pch w/o fp
Ostomy Supplies	A4383	Urinary rubber pouch w/o fp
Ostomy Supplies	A4384	Ostomy faceplt/silicone ring
Ostomy Supplies	A4385	Ost skn barrier sld ext wear
Ostomy Supplies	A4387	Ost clsd pouch w att st barr
Ostomy Supplies	A4388	Drainable pch w ex wear barr
Ostomy Supplies	A4389	Drainable pch w st wear barr
Ostomy Supplies	A4390	Drainable pch ex wear convex
Ostomy Supplies	A4391	Urinary pouch w ex wear barr
Ostomy Supplies	A4392	Urinary pouch w st wear barr
Ostomy Supplies	A4393	Urine pch w ex wear bar conv
Ostomy Supplies	A4394	Ostomy pouch liq deodorant
Ostomy Supplies	A4395	Ostomy pouch solid deodorant
Ostomy Supplies	A4396	Peristomal hernia supprt blt
Ostomy Supplies	A4398	Ostomy irrigation bag
Ostomy Supplies	A4399	Ostomy irrig cone/cath w brs
Ostomy Supplies	A4402*	Lubricant per ounce
Ostomy Supplies	A4404	Ostomy ring each
Ostomy Supplies	A4405	Nonpectin based ostomy paste
Ostomy Supplies	A4406	Pectin based ostomy paste
Ostomy Supplies	A4407	Ext wear ost skn barr <=4sq"
Ostomy Supplies	A4408	Ext wear ost skn barr >4sq"
Ostomy Supplies	A4409	Ost skn barr convex <=4 sq i
Ostomy Supplies	A4410	Ost skn barr extnd >4 sq
Ostomy Supplies	A4411	Ost skn barr extnd =4sq
Ostomy Supplies	A4412	Ost pouch drain high output
Ostomy Supplies	A4413	2 pc drainable ost pouch
Ostomy Supplies	A4414	Ost sknbar w/o conv<=4 sq in
Ostomy Supplies	A4415	Ost skn barr w/o conv >4 sqi
Ostomy Supplies	A4416	Ost pch clsd w barrier/fltr
Ostomy Supplies	A4417	Ost pch w bar/bltinconv/fltr
Ostomy Supplies	A4418	Ost pch clsd w/o bar w fltr
Ostomy Supplies	A4419	Ost pch for bar w flange/flt
Ostomy Supplies	A4420	Ost pch clsd for bar w lk fl
Ostomy Supplies	A4422	Ost pouch absorbent material
Ostomy Supplies	A4423	Ost pch for bar w lk fl/fltr
Ostomy Supplies	A4424	Ost pch drain w bar & filter
Ostomy Supplies	A4425	Ost pch drain for barrier fl

Product Category	HCPCS Level II Code	Short Description
Ostomy Supplies	A4426	Ost pch drain 2 piece system
Ostomy Supplies	A4427	Ost pch drain/barr lk flng/f
Ostomy Supplies	A4428	Urine ost pouch w faucet/tap
Ostomy Supplies	A4429	Urine ost pouch w bltinconv
Ostomy Supplies	A4430	Ost urine pch w b/bltin conv
Ostomy Supplies	A4431	Ost pch urine w barrier/tapv
Ostomy Supplies	A4432	Os pch urine w bar/fange/tap
Ostomy Supplies	A4433	Urine ost pch bar w lock fln
Ostomy Supplies	A4434	Ost pch urine w lock flng/ft
Ostomy Supplies	A4435	1pc ost pch drain hgh output
Ostomy Supplies	A4436	Irr supply sleev reus per mo
Ostomy Supplies	A4437	Irr supply sleev disp per mo
Ostomy Supplies	A4450*	Non-waterproof tape
Ostomy Supplies	A4452*	Waterproof tape
Ostomy Supplies	A4455*	Adhesive remover per ounce
Ostomy Supplies	A4456*	Adhesive remover, wipes
Ostomy Supplies	A5051	Pouch clsd w barr attached
Ostomy Supplies	A5052	Clsd ostomy pouch w/o barr
Ostomy Supplies	A5053	Clsd ostomy pouch faceplate
Ostomy Supplies	A5054	Clsd ostomy pouch w/flange
Ostomy Supplies	A5055	Stoma cap
Ostomy Supplies	A5056	1 pc ost pouch w filter
Ostomy Supplies	A5057	1 pc ost pou w built-in conv
Ostomy Supplies	A5061	Pouch drainable w barrier at
Ostomy Supplies	A5062	Drnble ostomy pouch w/o barr
Ostomy Supplies	A5063	Drain ostomy pouch w/flange
Ostomy Supplies	A5071	Urinary pouch w/barrier
Ostomy Supplies	A5072	Urinary pouch w/o barrier
Ostomy Supplies	A5073	Urinary pouch on barr w/flng
Ostomy Supplies	A5081	Stoma plug or seal, any type
Ostomy Supplies	A5082	Continent stoma catheter
Ostomy Supplies	A5083	Stoma absorptive cover
Ostomy Supplies	A5093	Ostomy accessory convex inse
Ostomy Supplies	A5102*	Bedside drain btl w/wo tube
Ostomy Supplies	A5120	Skin barrier, wipe or swab
Ostomy Supplies	A5121	Solid skin barrier 6x6
Ostomy Supplies	A5122	Solid skin barrier 8x8
Ostomy Supplies	A5126	Disk/foam pad +or- adhesive
Ostomy Supplies	A5131*	Appliance cleaner
Urological Supplies	A4217	Sterile water/saline, 500 ml
Urological Supplies	A4295	Straigh tip hydrophilic cath
Urological Supplies	A4296	Coude tip hydrophilic cath
Urological Supplies	A4297	Hydrophilic coat insert sup
Urological Supplies	A4310	Insert tray w/o bag/cath
Urological Supplies	A4311	Catheter w/o bag 2-way latex
Urological Supplies	A4312	Cath w/o bag 2-way silicone
Urological Supplies	A4313	Catheter w/bag 3-way
Urological Supplies	A4314	Cath w/drainage 2-way latex
Urological Supplies	A4315	Cath w/drainage 2-way silcne
Urological Supplies	A4316	Cath w/drainage 3-way
Urological Supplies	A4320	Irrigation tray
Urological Supplies	A4322	Irrigation syringe
Urological Supplies	A4326	Male external catheter
Urological Supplies	A4327	Fem urinary collect dev cup
Urological Supplies	A4328	Fem urinary collect pouch

Product Category	HCPCS Level II Code	Short Description
Urological Supplies	A4331*	Extension drainage tubing
Urological Supplies	A4332	Lube sterile packet
Urological Supplies	A4333	Urinary cath anchor device
Urological Supplies	A4334	Urinary cath leg strap
Urological Supplies	A4336	Urethral insert
Urological Supplies	A4338	Indwelling catheter latex
Urological Supplies	A4340	Indwelling catheter special
Urological Supplies	A4344	Cath indw foley 2 way silicn
Urological Supplies	A4346	Cath indw foley 3 way
Urological Supplies	A4349	Disposable male external cat
Urological Supplies	A4351	Straight tip urine catheter
Urological Supplies	A4352	Coude tip urinary catheter
Urological Supplies	A4353	Intermittent urinary cath
Urological Supplies	A4354	Cath insertion tray w/bag
Urological Supplies	A4355	Bladder irrigation tubing
Urological Supplies	A4356	Ext ureth clmp or compr dvc
Urological Supplies	A4357*	Bedside drainage bag
Urological Supplies	A4358	Urinary leg or abdomen bag
Urological Supplies	A4360	Disposable ext urethral dev
Urological Supplies	A4402*	Lubricant per ounce
Urological Supplies	A4450*	Non-waterproof tape
Urological Supplies	A4452*	Waterproof tape
Urological Supplies	A4455*	Adhesive remover per ounce
Urological Supplies	A4456*	Adhesive remover, wipes
Urological Supplies	A5102*	Bedside drain btl w/wo tube
Urological Supplies	A5105	Urinary suspensory
Urological Supplies	A5112	Urinary leg bag
Urological Supplies	A5113	Latex leg strap
Urological Supplies	A5114	Foam/fabric leg strap
Urological Supplies	A5131*	Appliance cleaner
Urological Supplies	A5200	Percutaneous catheter anchor

* HCPCS Level II codes included in product categories for ostomy supplies and urological supplies

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Specifically with regard to certain codes for lower volume items under the OTS Upper Extremity Braces and OTS Back Braces product categories, the average delivery distances were less than 100 miles as shown in tables 47 and 48. Although it does not appear that the braces falling under these codes are currently being delivered from remote locations, we still believe that they could be furnished by nationwide or regional contract suppliers. However,

we are soliciting comments on whether there is any reason that these codes should not be furnished on a mail order basis from remote supplier locations and instead should only be furnished on a non-mail order basis. The alternative would be to exclude codes that have a national average delivery distance of less than 100 miles and include them in future nationwide or regional competitions if the delivery distance for these codes increases to more than 100

miles. Excluding the items would mean that contract suppliers would not be required to furnish these braces, and we are concerned that this could potentially affect access to these items. However, contract suppliers would have discretion to furnish the items to beneficiaries on a non-mail order basis in addition to furnishing the items on a mail order basis, but contract suppliers would not be required to furnish the items on a non-mail order basis.

TABLE 47: NATIONAL AVERAGE DELIVERY DISTANCE FOR OTS UPPER EXTREMITY BRACES (2024)

HCPCS Level II Code	Average Distance	Allowed Charges
L3650	111	\$248,236
L3660	489	\$6,072,706
L3670	403	\$15,405,591
L3675	194	\$178,258
L3678	13	\$974
L3710	32	\$50,676
L3761	813	\$11,742,340
L3762	129	\$468,633
L3809	356	\$15,210,077
L3908	275	\$13,311,651
L3912	59	\$21,253
L3916	1,049	\$59,578,443
L3918	160	\$12,113
L3924	263	\$3,989,591
L3925	41	\$100,324
L3927	52	\$112,892
L3930	84	\$10,240

TABLE 48: NATIONAL AVERAGE DELIVERY DISTANCE FOR OTS BACK BRACES (2024)

HCPCS Level II Code	Average Distance	Allowed Charges
L0450	16	\$10,903
L0455	12	\$5,570
L0457	832	\$20,199,134
L0467	4	\$1,911
L0469	4	\$1,629
L0621	221	\$117,797
L0623	1,055	\$13,417
L0625	57	\$46,479
L0628	39	\$11,732
L0641	292	\$131,336
L0642	157	\$3,799,823
L0643	13	\$3,341
L0648	252	\$4,563,082
L0649	146	\$4,401
L0650	179	\$18,004,560
L0651	976	\$79,147,145

In the case of a RID CBP, the bid items would be delivered by the contract supplier to the beneficiary from a remote location, for example, through the mail. Items may be furnished to beneficiaries who come into the local storefront of a contract supplier, but we believe that most contract suppliers would have a limited number of local storefronts and therefore these occurrences would be rare. Again, contract suppliers would have discretion to furnish the items to

beneficiaries on a non-mail order basis in addition to furnishing the items on a mail order basis, but contract suppliers would not be required to furnish the items on a non-mail order basis.

We believe that situations where a beneficiary loses or is temporarily without supplies that Medicare has already paid for are rare. Claims for replacement supplies furnished from a supplier in these situations would be denied because Medicare has already paid for supplies for the time when the

replacement supplies are needed. The supplier of the replacement supplies would likely have the beneficiary sign an Advance Beneficiary Notice of Noncoverage (ABN), form CMS-R-131, making the beneficiary liable for the cost of the replacement supplies in the event the claim is denied. The beneficiary can appeal the denial of the claim for the replacement supplies, indicating the reason why the replacement supplies were needed, and the claim denial could potentially be

overturned on appeal. We are soliciting comment on our proposal that for supplies included under a RID CBP, these situations would continue to be handled the way they are now, through the claim appeals process. We are also soliciting comment on our proposal that obtaining replacement supplies from a local storefront owned by a non-contract supplier in these rare situations would not be a reason to deny a claim if it is determined that paying the claim for the replacement supplies would otherwise be reasonable.

3. Provisions of the Proposed Regulation

We are soliciting comments on our proposal to phase in a nationwide RID CBP or regional RID CBPs, to be defined under § 414.402, for product categories including items such as those listed in table 45 that typically are furnished to beneficiaries from remote supplier locations or locations that are hundreds of miles on average from the beneficiary residence under a future round of the DMEPOS CBP. The term “Remote item delivery competitive bidding program” would be defined under § 414.402 to mean “a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under the product category primarily to all Medicare beneficiaries regardless of where they live in the CBA. The CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country.” The term “Remote item delivery item” would be defined under § 414.402 to mean an item falling under a remote item delivery competitive bidding program that may be shipped or delivered to a beneficiary’s home, regardless of the method of delivery or picked up at a local pharmacy or supplier storefront if the beneficiary or caregiver for the beneficiary chooses to pick the item up in person. The product categories to be phased in under a RID CBP(s) would be designated through program instructions or by other means in accordance with existing regulations at 42 CFR 414.406(d). Contract suppliers serving a nationwide or regional RID CBP would be responsible for furnishing the items on either a mail order or non-mail order basis under the product category to all Medicare beneficiaries, regardless of where they live in the CBA. If a beneficiary who resides in a CBA receives an item in person at a local supplier storefront, that supplier would need to be a contract supplier for the item.

Items furnished to beneficiaries from remote supplier locations, such as those

listed in table 46 would be furnished in a nationwide RID CBP or regional RID CBPs that include both mail order and non-mail order items, and not under a “mail order” program that only includes mail order items.

G. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

Because CGMs and insulin infusion pumps are subject to rapid technological change, requiring frequent and substantial servicing, we are proposing to reclassify all CGMs and infusion pumps under the frequent and substantial servicing payment category at section 1834(a)(3) of the Act, as implemented under § 414.222(a). CMS would pay for all CGMs and insulin infusion pumps on a monthly rental basis under both the DMEPOS CBP and in non-CBAs under the fee schedule payments. The monthly rental payments would include payment for any necessary supplies and accessories. As further discussed later in this section, this would be a departure from how these items are currently paid under the Medicare DMEPOS fee schedule. Under the Medicare DMEPOS fee schedule, we typically pay for the purchase of CGMs, which are classified as routinely purchased equipment. Payment for insulin pumps is made on a capped rental basis, with beneficiaries taking over ownership of the pump after rental payments are made for 13 months of continuous use. In addition, we are proposing to allow contract suppliers to bill for up to 3 months of rental for these items in advance.

Class III devices are statutorily excluded from the DMEPOS CBP per section 1847(a)(2)(A) of the Act. Because certain brands of insulin infusion pumps are used in conjunction with class III CGMs, we propose that insulin infusion pumps used in conjunction with class III CGMs would also be excluded from the DMEPOS CBP. We want to avoid a situation where Medicare payments for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs are grossly excessive compared to Medicare payments for class II CGMs and insulin pumps that are not used in conjunction with class III CGMs. To avoid this, we propose that once class II CGMs and insulin infusion pumps are phased into the DMEPOS CBP, if the rental fee schedule amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs are more than 15 percent higher than the SPAs established for class II CGMs and insulin infusion pumps under the DMEPOS CBP, then we propose that we would adjust the fee schedule amounts

for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs to be equal to the SPAs established for class II CGMs and insulin infusion pumps under the DMEPOS CBP in accordance with the process described in § 405.502.

We are soliciting comments on these proposals.

1. Background

The Medicare Part B benefit for DME is primarily a benefit for rental of durable medical equipment such as wheelchairs, hospital beds, oxygen equipment, and ventilators for use in the beneficiary’s home, including certain institutions used as the beneficiary’s home. Various statutory payment provisions that added an option to purchase certain DME in lieu of rental or that cap total rental payments after a certain number of months or when total payments equal the purchase price for the equipment were phased in beginning in 1968. These statutory rules were intended to save money for the beneficiary and the Medicare program in cases where DME is needed on a long-term basis. However, we are concerned that two types of DME—CGMs and insulin infusion pumps—are classified under statutory provisions that limit beneficiary choice and access to newer technology, thereby limiting options for beneficiaries to improve their health and not accounting for the frequent and substantial servicing these devices require.

Medicare payment for CGM receivers can be made on a lump sum purchase basis or a monthly rental basis, although most Medicare beneficiaries receive the items on a purchase basis. Medicare pays for CGM receivers classified by the Food and Drug Administration (FDA) as class II or class III devices under the Federal Food, Drug, and Cosmetic Act. CGM systems can only be classified under class II if they can meet the requirements to be an integrated CGM system in accordance with Federal regulations at 21 CFR § 862.1355. Class III CGMs are not accurate enough to be classified as an integrated CGM system.

The 2025 average Medicare fee schedule amount for purchase of a new, class II CGM receiver is \$286.03. In addition to receiving payment for the purchase of the CGM receiver, suppliers are allowed to bill for replacement supplies necessary for the operation of the CGM every 90 days for a payment of \$803.76 for supplies used with class II CGMs, with total payments for the ongoing replacement of supplies accounting for over 98 percent of the total CGM costs over 5 years. CMS

issued program instructions on October 19, 2023 (Transmittal 12303; Change Request 13397) instructing Medicare Administrative Contractors (MAC) to allow CGM supplies to be billed in 90 day increments to align with longstanding practices in place for blood glucose monitors. In addition, the DME MAC Local Coverage Determinations for external infusion pumps allow suppliers to dispense up to 3 months of supplies at a time: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33794>.

Medicare payment for insulin infusion pumps is made on a capped rental basis, with beneficiaries taking ownership of the pump after rental payments are made for 13 months of continuous use. The rental payments over 13 months add up to \$5,702.34 for insulin pumps furnished in nonrural areas (metropolitan statistical areas) and \$5,926.87 for insulin pumps furnished in other, rural areas and non-contiguous areas of the United States (Alaska, Hawaii, Puerto Rico, etc.). In addition to receiving payment for rental of the insulin pump, suppliers are allowed to bill for replacement supplies necessary for the operation of the insulin pump every 90 days for a payment of approximately \$403.68 for nonrural areas and \$447.06 for rural and non-contiguous areas, with total payments for the ongoing replacement of supplies accounting for 60 percent of the total insulin pump costs, not including the cost of insulin, over 5 years.

In accordance with the payment rules for DME under section 1834(a) of the Act, DME items are classified under several different payment classes with different payment rules under section 1834(a)(2)(7) of the Act, added by section 4062(b) of the Omnibus Budget Reconciliation Act (OBRA) of 1987 (Pub. L. 100–203). In accordance with section 1834(a)(2)(A)(ii) of the Act and regulations at 42 CFR 414.220(a)(2), equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987 is considered routinely purchased equipment and can be paid on a rental or lump-sum purchase basis in accordance with the rules at section 1834(a)(2) of the Act and regulations at 42 CFR 414.220, but total payments for the equipment cannot exceed the purchase price for the item. Therefore, if the equipment is rented, the rental payments would cap at the point where total rental payments equal the Medicare fee schedule amount for purchase of the item. Although Medicare did not start covering CGMs

until 2017, blood glucose monitors, predecessors to the CGM, were acquired by purchase on a national basis more than 90 percent of the time during the period July 1986 through June 1987. As part of the final rule entitled “Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas,” published on December 28, 2021, CGMs were classified as routinely purchased equipment (FR 86 73900).

Since Medicare did not start covering insulin infusion pumps until 1994, they also were not acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. Other types of external infusion pumps that were covered as DME during the period July 1986 through June 1987 were not acquired by purchase on a national basis at least 75 percent of the time. Therefore, insulin infusion pumps are not classified as routinely purchased equipment in accordance with the statute and regulations and are not inexpensive equipment which can be paid in accordance with the rules at section 1834(a)(2) of the Act and regulations at 42 CFR 414.220. As such, insulin infusion pumps are classified as other covered items of DME and paid for in accordance with the capped rental payment rules at sections 1834(a)(7) and (8) of the Act and regulations at 42 CFR 414.229. Medicare pays a monthly rental amount for capped rental items for a period not to exceed 13 months of continuous use. “Continuous use” is defined in regulations at 42 CFR 414.230. After the 13-month capped rental period is over, the title to the equipment transfers to the beneficiary. In the case of both CGMs and insulin infusion pumps, Medicare makes separate payments on a purchase basis for supplies necessary for the effective use of the CGM or insulin infusion pump using fee schedule amounts calculated in accordance with section 1834(a)(6) and (8) of the Act.

Other than customized items of DME paid for in accordance with section 1834(a)(4) of the Act and regulations at 42 CFR 414.224 and oxygen and oxygen equipment paid for in accordance with section 1834(a)(5) and (9) of the Act and regulations at 42 CFR 414.226, CMS may classify an item as DME requiring frequent and substantial servicing paid

for in accordance with section 1834(a)(3) of the Act and regulations at 42 CFR 414.222 if the item requires frequent and substantial servicing in order to avoid risk to the patient's health. Payment for items falling under this class are made on a monthly rental basis, with rental payments continuing as long as coverage of the equipment under Part B continues and the equipment is being used in the home. The monthly rental amount includes payment for rental of the equipment, including maintenance and servicing of the equipment, and replacement of supplies and accessories necessary for the effective use of the DME. Separate payment is not allowed for supplies and accessories for items falling under this payment class.

We believe payment for CGMs and insulin infusion pumps should be on a continuous rental basis like other DME items requiring frequent and substantial servicing. The class of DME items requiring frequent and substantial servicing is described on page 392 of the House of Representatives Committee on the Budget Report 100–391 that accompanied OBRA 87 as items “that are technologically sophisticated and require frequent monitoring or adjustment in order to make sure they are functioning properly or being properly utilized by the patient. They are also typically quite expensive to purchase and often subject to relatively rapid technological change.” As we discuss in greater detail later in this section, CGMs and insulin infusion pumps are subject to rapid technological change and require frequent servicing by the supplier.

2. Current Issues

While Medicare beneficiaries enrolled under Part B who use CGM equipment generally use it on a long-term basis, making purchase of the equipment seem more practical than rental, the ongoing need to purchase replacement supplies for the equipment continues, and, in accordance with current regulations at 42 CFR 414.210(f)(a), the beneficiary is not able to obtain new, replacement CGMs or insulin pumps for 5 years unless the equipment is lost, stolen, or irreparably damaged. The technology for CGMs and insulin infusion pumps is rapidly evolving to be more accurate and to work in tandem, with combination CGM/insulin pump systems that regulate the administration of insulin based on patient need and even in anticipation of a patient's need. The American Diabetes Association (ADA) has also noted that diabetes technology is rapidly changing, but there is no “one-size-fits-all” approach

to technology use in people with diabetes. Per the ADA, insurance coverage can lag behind device availability, patient interest in devices and willingness to change can vary, and providers may have trouble keeping up with newly released technology.⁹⁰

We believe that the technology for CGMs and insulin infusion pumps, which are often used in conjunction with CGMs, will continue to change very rapidly in future years. In the CY 2022 DMEPOS final rule, commenters noted the rapid pace in changes in technology for CGMs and diabetes equipment in general. We discussed how glucose monitoring technology is changing rapidly, and the Medicare fee schedule amounts for this equipment should not be limited solely to the technology that is currently on the market (86 FR 73901). Rickson et al. (2023) have noted that seventeen new CGM devices have been introduced to the market during the past decade.⁹¹ Rickson et al. (2023) have also noted that the time between innovation and market launch for diabetes technologies is relatively short. New models with new features come onto the market often and physicians who treat patients with diabetes are frequently monitoring the patient's needs and whether they are properly utilizing their glucose monitoring and insulin infusion equipment. CGMs are used to alert the patient about dangerous glucose levels and to set insulin delivery rates or shut off insulin delivery via their infusion pumps, if necessary. Thus, it is vital that patients are using equipment with the latest features and technology to ensure that the measuring and displaying of glucose levels is as accurate as possible, so that the best information is available for both patient activated and equipment activated changes in diet and insulin.

Both CGMs and insulin pumps require software updates to ensure they are functioning properly and are protected from hacking or cyberattacks. Klonoff (2019) has noted the need for diabetes devices to meet established, sound security baselines in design and throughout the product's lifecycle.⁹² Klonoff (2015) also notes that everything about the importance of robust cybersecurity that is true for medical devices in general is particularly true for diabetes devices. Thus, software updates are often necessary to ensure the cybersecurity of diabetes devices

and prevent adverse events.⁹³ The FDA, for instance, in 2019 warned patients and health care providers that certain insulin pumps were being recalled due to potential cybersecurity risks, and recommended that patients using these models switch their insulin pump to models better equipped to protect against these potential risks.⁹⁴ The FDA noted that the cybersecurity vulnerabilities could allow a person to over deliver insulin to a patient, leading to low blood sugar (hypoglycemia), or to stop insulin delivery, leading to high blood sugar and diabetic ketoacidosis (a buildup of acids in the blood). For this recall, the manufacturer did not update the software, and instead opted to replace the device. However, Klonoff (2019) noted in response to this recall that insulin pump manufacturers should carefully review the cybersecurity of their products already on the market and provide software patches or updates when possible. Klonoff (2015) notes that patients with diabetes have a special need for impeccable data fidelity when they access their current glucose levels, glucose trend data, predictive data, insulin dosing records, hypoglycemia alerts, hyperglycemia alerts, blood pressure records, calorie information exercise records, and various reminders and timely notifications.

If beneficiaries are using rented CGM and/or insulin pump equipment, then the supplier of the rented equipment is responsible for making sure the equipment has the latest software updates and that the beneficiary is educated on how to use any updated software or features on the rented equipment. As the technology for these devices is rapidly changing and becoming more complex, beneficiaries may require more technical support from their supplier for any hardware or software issues. If either a CGM or insulin pump were to malfunction, for example provide inaccurate glucose measurements or insulin dosage, it would present an immediate health risk requiring urgent intervention. Suppliers of CGMs and insulin pumps must also adhere to frequent supply delivery schedules, as the supplies for these devices require frequent replacement so beneficiaries can maintain proper use of their equipment. Thus, we believe it is in the best interest of the beneficiary to classify CGMs and insulin pumps as items requiring frequent and substantial servicing.

We also believe that classifying CGMs and insulin pumps as items requiring frequent and substantial servicing, which would pay on a monthly rental basis in accordance section 1834(a)(3) of the Act under the fee schedule payment rules and under the DMEPOS CBP in accordance with regulations at 42 CFR 414.408(h)(8) and (j)(2)(iii), would have the additional benefit of allowing greater access to the latest technology equipment. This would eliminate beneficiary-ownership of the CGMs or insulin pumps for new patients but allow flexibility to switch to newer technology equipment and supplies more often than once every 5 years. The beneficiary would no longer be locked into the same CGM device or insulin pump technology for 5 years. Moreover, this would prevent the concerning scenario where beneficiaries rely on CGM or insulin pump technology that has lost manufacturer support, resulting in reduced software updates, discontinued security patches, or obsolete components. Such outdated technology poses significant risks to patient safety, data security, and therapeutic efficacy. By reclassifying these devices under the frequent and substantial servicing payment class, Medicare would ensure beneficiaries maintain access to current, fully supported technology that meets evolving safety and performance standards, which could ultimately reduce the potential for outdated device complications. The contract supplier of the rented equipment would be responsible for updating the software (including supporting the beneficiary with appropriately updating the software) and performing any other necessary maintenance and servicing of the equipment. The contract supplier would also be responsible for addressing recalls of the rented equipment and furnishing replacement equipment as necessary. As evidenced previously, the risk of recalls for this technology is real and serious if it were to occur. Under the DMEPOS CBP, the contract supplier would be required to furnish the CGM receiver or insulin pump ordered by the beneficiary's physician for use in treating diabetes, with the physician now being able to order changes in the equipment more frequently so that the beneficiary is able to take advantage of the latest equipment features and technology for managing diabetes. Over 98 percent of the cost of the CGM over 5 years is attributed to the frequent replacement of supplies and over 70 percent of the cost of the insulin pump over 5 years is

⁹⁰ <https://diabetes.org/sites/default/files/2023-09/dc22s007.pdf>.

⁹¹ <https://pubmed.ncbi.nlm.nih.gov/37306447/>.

⁹² <https://pmc.ncbi.nlm.nih.gov/articles/PMC6955451/>.

⁹³ <https://pmc.ncbi.nlm.nih.gov/articles/PMC4667325/>.

⁹⁴ <https://www.fda.gov/news-events/press-announcements/fda-warns-patients-and-health-care-providers-about-potential-cybersecurity-concerns-certain>.

attributed to the frequent replacement of supplies.

As discussed in section VII.F. of the preamble of this proposed rule, these items are currently delivered to beneficiaries from remote supplier locations that on average are hundreds of miles from the beneficiary's residence. In this section of the preamble of this proposed rule, we are proposing to establish a nationwide or regional CBP(s) for items such as CGMs and insulin pumps that may be phased in under future competitions. We are proposing to phase in payment on a monthly rental basis for CGMs and insulin pumps and all related supplies and accessories under the DMEPOS CBP. The monthly rental payments would continue as long as Medicare Part B coverage for the items continue. We are proposing to amend 42 CFR 414.412(b) to establish bid limits for CGMs and insulin infusion pumps for the first time they are phased in as the lead item in a product category under a nationwide or regional CBA(s). For CGMs, we are proposing that the bids submitted for rental of CGMs included as a lead item in a product category in a RID CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies for the CGM under subpart D of this part plus the average of the purchase fee schedule amounts that would otherwise apply to the CGM for the areas included in the RID CBP divided by 60 for the number of months over a 5-year period because the purchase fee schedule amount for the CGM receiver would cover use of the device for 5 years. Using 2025 fee schedule amounts to demonstrate how the bid limits would be calculated, for a nationwide CBP, the monthly fee schedule amount for the supplies for a non-adjunctive CGM (HCPCS level II code A4239) is \$267.92. The average of the 2025 fee schedule amounts for the purchase of a new, non-adjunctive CGM (HCPCS level II code E2103) with a reasonable useful lifetime of 5 years is \$286.03, which when divided by 60 generates a monthly payment of \$4.77. The 2025 bid limit for the bundled nationwide monthly rental payment for non-adjunctive, class II CGMs would therefore be \$272.69 (\$267.92 + \$4.77). Bidding entities competing to be a nationwide contract supplier for these items and other items in the same product category would need to submit bids that are lower than the bid limit (\$272.69 in this example) to be considered. Not factoring in reduced pricing under the DMEPOS CBP, beneficiary coinsurance payments would be the same as they are now for

the CGM receiver and monthly supplies, but the coinsurance payments for the CGM receiver would now be lower and spread out over 60 months rather than paid all at once in one lump sum.

Insulin infusion pumps were included under the DMEPOS CBP in nine CBAs from 2014 through 2016 as part of the product category for external infusion pumps. The fee schedule amounts for insulin infusion pumps and related supplies and accessories are adjusted based on the prices established under this round of the DMEPOS CBP. In accordance with current regulations at 42 CFR 414.210(g)(3), the fee schedule amounts for nonrural areas within the contiguous United States are adjusted based on 110 percent of the unweighted average of the nine SPAs in effect in 2016, which are updated on an annual basis in accordance with inflation update factors specified under 42 CFR 414.210(g)(4). The current nonrural 2025 fee schedule amount for rental of an insulin infusion pump (HCPCS level II code E0784) is \$543.08. The current nonrural 2025 fee schedule amount for the weekly supplies for an insulin infusion pump (HCPCS level II code A4224) is \$25.19, and the current nonrural 2025 fee schedule amount for one sterile syringe type cartridge supply for an insulin infusion pump (HCPCS level II code A4225) is \$3.38. By comparison, the 2025 adjusted fee schedule amounts for these items when furnished to beneficiaries in rural areas within the contiguous United States and areas outside the contiguous United States are much higher. The average of the 2025 fee schedule amounts for these areas is \$565.51 for HCPCS level II code E0784, \$28.50 for HCPCS level II code A4224, and \$3.54 for HCPCS level II code A4225. The higher fee schedule amounts established for these areas in accordance with regulations at 42 CFR 414.210(g)(2)(ii) and (iii) account for higher costs of suppliers furnishing items in these areas. However, these items are being furnished mostly by mail to beneficiaries across the nation from remote supplier locations. The cost of shipping an item from a remote location to a beneficiary residing in a rural area is typically no higher than the cost of shipping an item from a remote location to a beneficiary residing in a nonrural area. Additional shipping and handling costs may be incurred in some cases for items that are shipped to an area outside the contiguous United States such as Alaska, Hawaii, or Puerto Rico, but there are very few beneficiaries living in these areas compared to areas within the contiguous United States.

For insulin pumps, we are soliciting comments on our proposal that the bids submitted for rental of insulin infusion pumps included as a lead item in a product category under the DMEPOS CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies and accessories for the equipment under subpart D of this part for nonrural areas for a one month period plus the total rental fee schedule amounts that would otherwise apply to rental of the insulin pump for 13 months of continuous use under subpart D of this part for nonrural areas divided by 60. The payment amount that would otherwise apply to the supplies and accessories for insulin pumps would be calculated using the nonrural weekly fee schedule amount for supplies paid using HCPCS level II code A4224 multiplied by four plus the nonrural fee schedule amount for nine sterile, syringe type cartridges paid using HCPCS level II code A4225. In 2024, Medicare paid for seven to nine units of A4225 per month on average for beneficiaries using insulin infusion pumps (HCPCS code E0784). We are soliciting comments on our proposal to use nine units for the one-month supply calculation as this represents the upper range currently being paid for by Medicare on a monthly basis and therefore builds in sufficient payment to ensure this quantity of supplies can continue to be furnished. Using 2025 fee schedule amounts to demonstrate how the bid limits would be calculated, for a nationwide CBP, the weekly nonrural 2025 fee schedule amount for the supplies for an insulin infusion pump (HCPCS level II code A4224) is \$25.19 and the monthly allowance is \$100.76 (\$25.19 multiplied by four). The nonrural 2025 fee schedule amount for one sterile syringe type cartridge for an insulin infusion pump (HCPCS level II code A4225) is \$3.38 and the monthly allowance is \$30.42 (\$3.38 multiplied by nine). The total nonrural 2025 rental payments for the insulin infusion pump over 13 months is \$5,702.34 and the monthly allowance is \$95.04 (\$5,702.34 divided by 60 for the number of months over 5 years). The 2025 bid limit for the bundled nationwide monthly rental payment for insulin pumps would therefore be \$226.22 (\$100.76 + \$30.42 + \$95.04). Bidding entities competing to be a nationwide contract supplier for these items and other items in the same product category would need to submit bids that are lower than the bid limit (\$226.22 in this example) to be considered. Not factoring in reduced pricing under the DMEPOS CBP, for beneficiaries that begin using insulin

pumps once the new rules would take effect, coinsurance payments would be approximately the same as they are now for the insulin pumps and monthly supplies and accessories, but the coinsurance payments for the insulin pump would now be lower and spread out over 60 months rather than over 13 months. For beneficiaries who own their insulin infusion pump, coinsurance payments would remain approximately the same unless they elect to obtain a new insulin pump, which would result in new monthly coinsurance payments that include payment for the pump as well as the supplies and accessories for the pump. For beneficiaries who are in the middle of the 13-month capped rental period at the time the pumps are phased into the DMEPOS CBP and the new rules would take effect, their coinsurance payments would increase since they would transition to the new monthly payments with coinsurance payments which would not be reduced by the amounts attributed to the monthly rental payments already made under the capped rental rules. However, the payments made overall should be reduced under the DMEPOS CBP and therefore the net change in beneficiary coinsurance after factoring in the competitive bidding price reductions should be a reduction in cost sharing across the board.

We are soliciting comments on our proposal to make corresponding changes to the regulations for determining competitive bidding payment amounts for non-lead items at 42 CFR 414.416(b) to reflect how to use the bid amounts to calculate the monthly payments for the non-lead items. We are soliciting comments on our proposal that the SPAs for the rental of a non-lead item in a product category including CGMs and insulin infusion pumps would be established in a manner that is consistent with how SPAs are established currently for non-lead items in accordance with § 414.416(b). Currently the SPA for a non-lead item is equal to the SPA for the lead item multiplied by the ratio of the 2015 fee schedule amount for the non-lead item for each area to the 2015 fee schedule amount for the lead item for the same area. Our methodology for calculating SPAs for non-lead items is based on the difference in the unadjusted fee schedule amounts for the lead item compared to the non-lead item. We use the 2015 fee schedule amounts for this purpose as this was the last year the DMEPOS fee schedule amounts were not adjusted based on pricing from the DMEPOS CBP. The fee schedule amounts for insulin pumps

were adjusted using pricing from the DMEPOS CBP. Given the possibility that CGMs and insulin pumps would be included in the same product category (with CGMs being the lead item), we are proposing to calculate what the unadjusted fee schedule amounts for CGMs would have been in 2015 so we can compare that to the unadjusted fee schedule amounts for insulin pumps from 2015 for the purpose of calculating the non-lead item SPAs for the insulin pumps. We are soliciting comments on our proposal that the 2015 fee schedule amounts for the monthly rental of a class II CGM would be calculated using the 2025 fee schedule amounts and removing the fee schedule update factors from 2016 through 2025 to convert the 2025 fee schedule amounts to 2015 fee schedule amounts. We are also soliciting comments on our proposal to then add the 2015 fee schedule amount for the monthly supplies for a class II CGM to the average of the 2015 fee schedule amounts for the purchase of a new class II CGM divided by 60 for the areas included in the CBA. The conversion of the fee schedule amounts to 2015 fee schedule amounts is necessary because the methodology under § 414.416(b) uses the ratio of unadjusted fee schedule amounts from 2015 (the year before the DMEPOS CBP was implemented) between the non-lead item and the lead item multiplied by the SPA for the lead item to establish the SPA for the non-lead item and because Medicare did not start paying for class II CGMs until after 2015.

We are soliciting comments on our proposal that the 2015 fee schedule amounts for the monthly rental of an insulin infusion pump would be calculated using the average 2015 fee schedule amounts for the insulin infusion pump multiplied by 10.5 and divided by 60 for the nonrural areas included in the RID CBP, and then adding the average 2015 fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by nine for the nonrural areas included in the RID CBP plus the average 2015 fee schedule amounts for the weekly insulin pump supplies multiplied by four for the nonrural areas included in the RID CBP. The average 2015 fee schedule amounts for the insulin infusion pump multiplied by 10.5 equals the total rental payments made over the 13-month capped rental period.

DME items that are class III devices under the Federal Food, Drug, and Cosmetic Act are excluded from the DMEPOS CBP by section 1847(a)(2)(A) of the Act. Federal Food, Drug, and

Cosmetic Act classifies medical devices into three classes based on the level of control needed to ensure their safety and effectiveness. Class I devices are considered low risk and are subject to general controls. Class II devices are considered moderate risk and are subject to general controls and special, device-specific controls. Class III devices are considered high risk and are subject to general controls and premarket approval, the most stringent device marketing application required by the FDA. Class III CGMs are excluded from the DMEPOS CBP by section 1847(a)(2)(A) of the Act. In addition, there are some insulin infusion pumps that are approved by the FDA for use in conjunction with a class III CGM. In instances where an insulin infusion pump that has been approved by the FDA for use in conjunction with a class III CGM is being used in conjunction with a class III CGM, we believe the insulin pumps should be excluded from the DMEPOS CBP as well. We are soliciting comments on this proposal to exclude insulin pumps used in conjunction with a class III CGM from the DMEPOS CBP under these circumstances.

a. Medicare Part B Payment for Class III CGMs and Insulin Pumps Used in Conjunction With Class III CGMs

Because class III CGMs are excluded from the DMEPOS CBP by statute and we are proposing that insulin infusion pumps used in conjunction with class III CGMs would also be excluded from the DMEPOS CBP, we believe it is necessary to use the authority at section 1842(b)(8) of the Act to limit the payment amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs to the level established for class II CGMs and insulin infusion pumps that are used alone or in conjunction with a class II CGM under the CBP.

As discussed previously, class III CGMs are statutorily excluded from the DMEPOS CBP and are less accurate than class II CGMs. We believe that lowering the Medicare payment amounts for class II CGMs and class II insulin infusion pumps under the DMEPOS CBP and maintaining higher payments for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs under the Medicare fee schedule for DME would encourage a shift from more accurate class II CGMs and insulin pumps to less accurate class III CGMs and insulin pumps. To prevent this from happening, we are therefore proposing to adjust the fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class

III CGM to equal the payment amounts established for class II CGMs and insulin pumps under the DMEPOS CBP.

In order to make proposals to use the authority at section 1842(b)(8) of the Act to adjust the fee schedule payment amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs, the process mandated by section 1842(b)(9) of the Act and its implementing regulations at 42 CFR 405.502(g) and (h) apply. We expect that reductions in the payment amounts for class II CGMs and insulin pumps under the DMEPOS CBP would result in payment amounts for these items that are more than 15 percent below the fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs. We are proposing that in situations where the Medicare bundled monthly rental payment amounts for class II CGMs and/or insulin pumps under the DMEPOS CBP are more than 15 percent lower than the Medicare bundled monthly rental fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs, that the Medicare bundled monthly rental fee schedule amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs would be adjusted so that they are equal to the bundled monthly rental payment amounts established under the DMEPOS CBP for the class II CGMs and insulin pumps.

b. Medicare Part B Fee Schedule Payments for Class II CGMs and Insulin Pumps

We are not proposing to utilize the inherent reasonableness authority at 42 CFR 405.502(g) and (h) to adjust the prices of class II CGMs or insulin infusion pumps paid under Medicare Part B. In accordance with section 1834(a)(1)(F)(i) of the Act, the payment basis for class II CGMs and insulin infusion pumps furnished in a CBA is the payment basis determined under the CBP. In accordance with section 1834(a)(1)(F)(ii) and (iii) of the Act, we soliciting comments on our proposal that the fee schedule amounts for class II CGMs or insulin infusion pumps would be adjusted based on information on the payment determined under the CBP for the rental of the equipment using the methodology established in regulations at 42 CFR 414.210(g). For the same reasons discussed previously for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs, in any situation where payment for class II CGMs or insulin infusion pumps not used in conjunction with class III CGMs are paid for in

accordance with the fee schedule payment basis at section 1834(a)(1)(B) of the Act in an areas that is not a CBA following the phase in of these items under the DMEPOS CBP, these items would be classified as items requiring frequent and substantial servicing under section 1834(a)(3) of the Act.

3. Provisions of the Proposed Regulation

a. Payment for CGMs and Insulin Pumps Furnished by Contract Suppliers Under the DMEPOS CBP and by Grandfathered Suppliers

We are soliciting comments on our proposal to make payment on a monthly rental basis for CGMs and insulin pumps furnished by contract suppliers under the DMEPOS CBP and by non-contract, grandfathered suppliers in accordance with section 1847(a)(4) of the Act, which allows rental agreements for covered CGMs and insulin pumps entered into before the application of the DMEPOS CBP to be continued once the items are phased in under the program, on a bundled monthly rental basis in accordance with regulations at 42 CFR 414.408(h)(8) and (j)(2)(iii), respectively. Payment would be based on SPAs for the bundled, monthly rental of the items for both the contract suppliers and non-contract grandfathered suppliers. Separate payment for supplies and accessories for the equipment would no longer be made and contract suppliers would retain ownership of the rental equipment.

b. Bids Submitted for Class II CGMs or Insulin Pumps Included as a Lead Item in a Product Category for the First Time

We are soliciting comments on our proposal to amend the regulations at 42 CFR 414.412 to specify that the bids submitted for rental of CGMs included as a lead item in a product category under the DMEPOS CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies for the equipment under subpart D plus the average of the purchase fee schedule amounts that would otherwise apply to the CGM (HCPCS level II code E2103) for the areas included in the CBA divided by 60.

We are also soliciting comments on our proposal to amend the regulations at 42 CFR 414.412 to specify that the bids submitted for rental of insulin infusion pumps included as a lead item in a product category under the DMEPOS CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies and accessories for the equipment under subpart D of this part for nonrural areas for a one month

period plus the total rental fee schedule amounts that would otherwise apply to rental of the insulin pump for 13 months of continuous use under subpart D of this part for nonrural areas divided by 60. The payment amount that would otherwise apply to the supplies and accessories for insulin pumps would be calculated using the nonrural weekly fee schedule amount for supplies paid using HCPCS level II code A4224 multiplied by four plus the nonrural fee schedule amount for nine sterile, syringe type cartridges paid using HCPCS level II code A4225.

c. Separate Payment for Replacement of Supplies and Accessories for Class II CGMs and Insulin Pumps Owned by the Beneficiary at the Time These Items Are Phased in Under the DMEPOS CBP for the First Time in a CBA

We are soliciting comments on our proposal that separate payment can continue to be made under the DMEPOS CBP for replacement of supplies and accessories necessary for the effective use of a CGM or insulin pump owned by the beneficiary at the time these items are phased in under the DMEPOS CBP for the first time in a CBA. The beneficiary would continue to own the CGM or insulin pump and would receive replacement supplies and accessories for the CGM or insulin pump from a contract supplier for the CBA where they reside. This is a temporary transition rule that would phase out once all beneficiary-owned CGMs or insulin pumps are replaced by rented equipment after they are lost, stolen, irreparably damaged, have been in use for the equipment's 5-year reasonable useful lifetime. During this transition period, SPAs for the monthly supplies and accessories for a beneficiary-owned CGM or insulin pump would be established in accordance with the payment rules for non-lead items under proposed regulations at 42 CFR 414.416(b)(4) summarized in section VII.G. As noted previously, we are proposing that the beneficiary would have the option to transition from the use of the equipment they own to use of a rented CGM and/or insulin pump from a contract supplier at any time.

d. Calculating SPAs for Class II CGMs, Insulin Pumps, and Supplies and Accessories for Beneficiary-Owned Class II CGMs and Insulin Pumps Furnished as Non-Lead Items in a Remote Item Delivery CBP

We are soliciting comments on our proposal to amend existing regulations at 42 CFR 414.416(b) by adding paragraph (4) to establish the

methodologies for calculating the SPAs for items furnished as non-lead items under product categories in a RID CBP for the monthly rental of class II CGMs, the monthly rental of insulin infusion pumps, the monthly supplies for a beneficiary-owned class II CGM, and the monthly supplies and accessories for a beneficiary-owned insulin infusion pump in a manner consistent with existing regulations at 42 CFR 414.416 which bases the SPAs for the lead item in a product category and CBA on the bids submitted and the SPAs for each non-lead item in the same product category and CBA based on the 2015 fee schedule amount for the non-lead item divided by the 2015 fee schedule amount for the lead item multiplied by the SPA for the lead item.

We are also soliciting comments on our proposed methodologies for calculating the 2015 fee schedule amounts for the monthly rental of class II CGMs, the monthly rental of insulin infusion pumps, the monthly supplies for a beneficiary-owned class II CGM, and the monthly supplies and accessories for a beneficiary-owned insulin infusion pump under paragraphs (i) through (iv) of § 414.416(b)(4) as follows:

- The 2015 fee schedule amounts for the monthly bundle that includes a CGM and supplies are calculated using the 2025 fee schedule amounts and removing the fee schedule update factors from 2016 through 2025, and then adding the 2015 fee schedule amount for the supplies to the average of the 2015 fee schedule amounts for the purchase of a new CGM divided by 60 for the areas included in the RID CBP.
- The 2015 fee schedule amount for the monthly supplies for a CGM owned by a beneficiary is calculated using the 2025 fee schedule amount and removing the fee schedule update factors from 2016 through 2025.
- The 2015 fee schedule amounts for the monthly bundle that includes an insulin infusion pump and supplies and accessories are calculated using the average 2015 nonrural fee schedule amounts for the insulin infusion pump multiplied by 10.5 and divided by 60 for the areas included in the RID CBP, and then adding the average 2015 nonrural fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by nine for the areas included in the RID CBP plus the average 2015 nonrural fee schedule amounts for the weekly insulin pump supplies multiplied by four for the areas included in the RID CBP.
- The 2015 fee schedule amounts for the monthly bundle that includes the supplies and accessories for an insulin

infusion pump owned by a beneficiary is calculated using the average 2015 nonrural fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by nine for the areas included in the RID CBP plus the average 2015 nonrural fee schedule amounts for the weekly insulin pump supplies multiplied by four for the areas included in the RID CBP.

e. Insulin Infusion Pumps Used in Conjunction With Class III CGM

We are soliciting comments on our proposal that in instances where an insulin infusion pump that has been approved by the FDA for use in conjunction with a class III CGM is being used in conjunction with a class III CGM, both the insulin pump and the class III CGM would be excluded from the DMEPOS CBP.

f. Payment Reclassification of CGMs and Insulin Infusion Pumps

We are soliciting comments on our proposal to reclassify all CGMs and insulin infusion pumps paid for in accordance with the rules at section 1834(a) of the Act as items requiring frequent and substantial servicing under section 1834(a)(3) of the Act and regulations at 42 CFR 414.222 for the reasons highlighted in section VII.A.

g. Special Payment Limits for Class III CGMs and Insulin Infusion Pumps Used in Conjunction With Class III CGMs

With regard to class III CGMs excluded from the DMEPOS CBP by section 1847(a)(2)(A) of the Act and insulin infusion pumps used in conjunction with class III CGMs, we are soliciting comments on our proposal to use the authority at section 1842(b)(8) of the Act to establish special payment limits for these items if the bundled monthly rental amounts for class II CGMs and/or insulin infusion pumps established under the DMEPOS CBP are at least 15 percent below the bundled monthly rental fee schedule amounts for the class III CGMs and related supplies and insulin infusion pumps and related supplies established in accordance with section 1834(a)(3) of the Act. In accordance with § 405.502(g)(1)(ii), a payment amount can be considered grossly excessive and can be adjusted using the authority under section 1842(b)(8) of the Act and process outlined in section 1842(b)(9) of the Act and regulations at § 405.502(g) if it is determined that an overall payment adjustment of 15 percent or more is necessary to produce a realistic and equitable payment amount. We believe it is realistic to conclude that suppliers

of class III CGMs and insulin pumps used in conjunction with class III CGMs would be able to furnish class III CGMs and insulin pumps at the payment amounts established for class II CGMs and insulin pumps under the DMEPOS CBP. We believe the bids obtained for class II CGMs and insulin pumps under the DMEPOS CBP that are determined to be bona fide is valid and reliable data for use in establishing realistic payment amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs. We believe it would not be equitable to pay more for a class III CGM and/or insulin pump than a class II CGM and/or insulin pump because class III CGMs are less accurate than class II CGMs. We believe that a reduction in payment for class II CGMs and/or insulin pumps under the DMEPOS CBP of greater than 15 percent indicates that the fee schedule amounts for these items were grossly excessive. We believe that if the fee schedule amounts for class III CGMs and/or insulin pumps used in conjunction with class III CGMs are more than 15 percent higher than the payment amounts established for class II CGMs and/or insulin pumps under the DMEPOS CBP, that the fee schedule amounts for class III CGMs and/or insulin pumps used in conjunction with class III CGMs are grossly excessive. We believe that similar conclusions can be made regarding supplies and accessories used in conjunction with class III CGMs and insulin pumps used in conjunction with class III CGMs owned by the beneficiary at the time class II CGMs and insulin pumps are phased in under the DMEPOS CBP. We believe it is realistic and equitable to establish the payment amounts for these supplies and accessories based on the payment amounts established under the DMEPOS CBP for supplies and accessories used in conjunction with beneficiary-owned class II CGMs and insulin pumps. Separate payment for supplies and accessories for beneficiary-owned class III CGMs and insulin pumps used in conjunction with class III CGMs would no longer be made once the 5-year reasonable useful lifetime for the beneficiary-owned equipment has expired. Medicare payment for class II CGMs and insulin pumps would be established under the DMEPOS CBP and therefore the fee schedule amounts for these items would not be adjusted using the authority under section 1842(b)(8) of the Act. We are also soliciting comments on our proposal that the monthly rental fee schedule payment amounts for class III CGMs would be limited to the monthly rental SPAs established for class II CGMs under the

DMEPOS CBP. We are proposing that the monthly rental fee schedule payment amounts for insulin pumps used in conjunction with class III CGMs would be limited to the monthly rental SPAs established for insulin pumps under the DMEPOS CBP. We are soliciting comments on our proposal that the monthly fee schedule payment amounts for supplies used in conjunction with beneficiary-owned class III CGMs would be limited to the monthly SPAs established for supplies used in conjunction with beneficiary-owned class II CGMs under the DMEPOS CBP. We are also soliciting comments on our proposal that the monthly fee schedule payment amounts for supplies and accessories used in conjunction with beneficiary-owned insulin pumps that are used in conjunction with class III CGMs would be limited to the monthly SPAs established for supplies and accessories used in conjunction with beneficiary-owned insulin pumps under the DMEPOS CBP.

In accordance with section 1842(b)(8)(C)(ii) of the Act, we believe that the payment amounts for class III CGMs, insulin pumps used in conjunction with class III CGMs, and supplies and accessories used in conjunction with beneficiary-owned class III CGMs and insulin pumps used in conjunction with class III CGMs do not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs. If the fee schedule payment amounts for class II CGMs and insulin pumps are reduced by more than 15 percent under the DMEPOS CBP, then this is an indication that the cost of furnishing these items is significantly lower than the fee schedule amounts for these items. We believe the same would also be true for class III CGMs and insulin pumps used in conjunction with class III CGMs as we believe the acquisition and production costs of class III CGMs and insulin pumps used in conjunction with class III CGMs are similar to the acquisition and production costs of class II CGMs and insulin pumps that are not used in conjunction with class III CGMs. The equipment is used for the same purpose and includes the same covered features of continuous glucose monitoring and pumping of insulin. In the case of CGMs, manufacturers of class II CGMs have invested in making the equipment more accurate and therefore the acquisition and production costs of class II CGMs may be higher than the acquisition and production costs of class III CGMs. Insulin pumps used in

conjunction with class III CGMs perform the same covered function as insulin pumps that are not used in conjunction with class III CGMs. We believe it is therefore realistic and equitable to pay no more for a class III CGM or insulin pump used in conjunction with a class III CGM than the payment amount established under the DMEPOS CBP for a class II CGM or insulin pump.

In accordance with section 1842(b)(9)(A) of the Act, the Secretary shall consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under section 1842(b)(8)(B) of the Act to reduce payment for the item or service by more than 15 percent for a year. The corresponding regulations at 42 CFR 405.502(g)(3) require CMS to publish in the **Federal Register** proposed and final notices announcing a special payment limit before it adopts the limit. Regarding special payment limit adjustments greater than 15 percent of the payment amount, 42 CFR 405.502(h)(3) requires that before making a determination that a payment amount for a category of items or services is not inherently reasonable by reason of its grossly excessive or deficient amount, CMS consult with representatives of the supplier industry likely to be affected by the change in the payment amount. CMS must publish in the **Federal Register** the proposed and final notices of a special payment limit before it adopts the limit. Therefore, as part of this proposed rule, we are soliciting comments from representatives of suppliers or other individuals who furnish class III CGMs, insulin pumps used in conjunction with class III CGMs, and supplies and accessories used in conjunction with beneficiary-owned class III CGMs or beneficiary-owned insulin pumps used in conjunction with class III CGMs on the proposed payment reductions for these items and services.

In accordance with section 1842(b)(9)(B)(iii) of the Act and the corresponding regulations at 42 CFR 405.502(h), when the proposed special payment limit adjustments are greater than 15 percent of the payment amount within a year, CMS must consider in a proposed and final notice the potential impacts of the proposed payment reductions on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates. We propose that the payment amounts for class III CGM suppliers and manufacturers would be reduced, but at the same rate as class II CGM suppliers and manufacturers, avoiding the potential impact of

providing a financial incentive to increase access to less accurate class III CGMs and decrease access to more accurate class II CGMs. We are soliciting comments on the proposed reductions in payment and believe they would level the playing field and avoid providing class III CGM suppliers and manufacturers with an unfair advantage. The quality of CGMs in general would not be impacted and if anything would be preserved since contract suppliers would not have a financial incentive to furnish class III CGMs in place of class II CGMs. Class III CGMs currently make up about 25 percent of total allowed charges for CGMs under Medicare and so any impact resulting from the proposed reductions in payment for class III CGMs would be significantly less than any impact resulting from payment reductions for class II CGMs under the DMEPOS CBP. We therefore believe the proposed payment special payment limits and special payment method for class III CGMs and insulin pumps would have a minimal impact on the CGM and insulin pump industry in general. The impact on access to CGMs in general as a result of the special payment limit and method of payment would also therefore be minimal. Beneficiary cost-sharing for class III CGMs, insulin pumps used in conjunction with class III CGMs, and supplies and accessories used with beneficiary-owned class III CGMs and insulin pumps would be reduced as a result of the special payment limit and method. Program savings would also be achieved for these items. Assignment rates and participation rates would likely not be affected as a result of the proposed special payment limits and payment method as payment for the cost of furnishing class III CGMs and insulin pumps on assignment-related basis would be based on the payment established under the DMEPOS CBP based on bids submitted by bidding entities for furnishing class II CGMs and insulin pumps on an assignment-related basis for all beneficiaries under the DMEPOS CBP. Under the DMEPOS CBP, contract suppliers of class II CGMs and insulin pumps are required to accept assignment of all claims for furnishing these items by section 1847(b)(5)(C) of the Act. Suppliers of class III CGMs know that if they do not accept assignment of the claims for the class III CGMs or insulin pumps used in conjunction with class III CGMs, their customers could switch to a class II CGM supplier or supplier of an insulin pump that is not used in conjunction with a class III CGM to avoid the

financial liability associated with unassigned claims.

h. Advance Billing for Three Months of Rental

Payment for supplies and accessories used with a beneficiary-owned class II or class III CGM or a beneficiary-owned

insulin infusion pump is currently made for these items in quantities necessary for a 90-day period. We are soliciting comments on a proposal to allow contract suppliers to bill for up to 3 months of rental for CGMs and insulin infusion pumps in advance to be consistent with this policy.

i. Summary of Proposed Provisions

The following is a summary list of the proposed provisions under this section for which we are soliciting comments:

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Proposed Payment Rules for Class II CGMs and Insulin Infusion Pumps that are not used in Conjunction with Class III CGMs and are Furnished under the DMEPOS CBP

- Payment would be on a continuous rental basis with payment for use of the equipment and all necessary supplies and accessories included in monthly rental payments made for up to 3 months in advance. Contract suppliers retain ownership of the rented equipment.
- Payment for replacement of supplies and accessories only for beneficiary-owned equipment at the start of the program in a CBA would continue to be made as separate items under the product category until the beneficiary-owned equipment is replaced because it is lost, stolen, irreparably damaged, has exceeded the reasonable useful lifetime (as defined at 42 CFR 414.210(f)(1)), or in cases where the beneficiary elects to obtain newer equipment. Beneficiaries who own their equipment and want to replace the equipment with new equipment would have the option to obtain new rented equipment from a contract supplier at any time.
- Rental agreements for equipment in place at the time the new rules are phased in under a CBA may be continued under the existing grandfathering rules for items requiring frequent and substantial servicing. Payment to grandfathered suppliers would be based on the monthly rental payment amounts established under the DMEPOS CBP.
- If the class II CGM is the lead item in the product category the first time the new payment rules are implemented in a CBA, the bid limit would be established based on the monthly fee schedule amount for the replacement supplies plus the average purchase new fee schedule amount for the CGM for the areas included in the CBA divided by 60.
- If the insulin pump is the lead item in the product category the first time the new payment rules are implemented in a CBA, the bid limit would be established based on the average weekly fee schedule amount for the replacement supplies and accessories for the areas included in the CBA multiplied by four, plus the average fee schedule amount for the syringe type cartridge for the areas included in the CBA multiplied by nine, plus the average of the total rental fee schedule amounts over 13 months for the insulin pump for the areas included in the CBA divided by 60.

Proposed Payment Rules for Class III CGMs and Insulin Infusion Pumps used in Conjunction with Class III CGMs (to be effective on the date the new rules for Class II CGMs and Insulin Pumps are Implemented)

- All CGM and insulin pump equipment would be classified as items requiring frequent and substantial servicing for the purposes of implementing the payment rules under section 1834(a) of the Act. Payment would be on a continuous rental basis with payment for use of the equipment and all necessary supplies and accessories included in monthly rental payments made for up to 3 months in advance. Contract suppliers retain ownership of the rented equipment.
- Special payment limits would be established in accordance with regulations at 42 CFR 405.502(g) and sections 1842(b)(8) and (9) of the Act to limit payment for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs as well as supplies and accessories for beneficiary owned class III CGMs and insulin infusion pumps used in conjunction with class III CGMs to the payment amounts established for class II CGMs and insulin infusion pumps as well as supplies and accessories for beneficiary owned class II CGMs and insulin infusion pumps under the DMEPOS CBP.
- Payment for replacement of supplies and accessories only for beneficiary-owned equipment would continue to be made as separate items after the implementation date of the CBP until the beneficiary-owned equipment is replaced because it is lost, stolen, irreparably damaged, is more than 5 years old, or in cases where the beneficiary elects to obtain newer equipment.

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H. Revising the Submission of Financial Document Requirements for the DMEPOS CBP

1. Background

Section 1847(b)(2) of the Social Security Act (Act) outlines the conditions for awarding a DMEPOS CBP supplier contract. Section 1847(b)(2)(A)(ii) of the Act specifies that CMS may not award a contract to any entity under the competition conducted in a competitive acquisition area unless the Secretary finds that the entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

Section 1847(a)(1)(F) of the Act applies to supplier feedback on missing financial documentation. Section 1847(a)(1)(F)(iv) of the Act defines a covered document as “a financial, tax, or other document required to be submitted by a bidding entity as part of an original bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.” If a covered document is submitted to CMS by the CDRD and one or more covered documents is missing, per section 1847(a)(1)(F)(i)(I) of the Act, the

Secretary is required to provide notice no later than 45 days (in the first round of competition acquisition program as described in subparagraph (B)(i)(I)) or 90 days (in subsequent rounds of such programs) after the CDRD. Per section 1847(a)(1)(F)(ii)(I) and (II) of the Act, the CDRD is the date that is 30 days before the final date specified by the Secretary for submission of bids under the program or the date that is 30 days after the first date specified by the Secretary for submission of bids under the program.

Section 1847(a)(1)(F)(i)(II) of the Act specifies that the Secretary may not reject the bid submission on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidding entity is submitted to the Secretary no later than 10 business days after the date of such notice. Per the limitations of this process in section 1847(a)(1)(F)(iii)(I)–(IV) of the Act, it applies only to the timely submission of covered documents, does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether the documents meet applicable requirements, shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II) of section 1847(a)(1)(F) of

the Act, and shall not be construed as permitting a bidding entity to change bidding amounts or to make other changes in a bid submission.

In the 2006 proposed rule (71 FR 25675), CMS proposed that, as part of the bid selection process, the Request for Bids (RFB) will identify the specific information CMS requires to evaluate bidding entities, which may include: a bidding entity’s bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency.

In the 2007 final rule (72 FR 18037), CMS responded to comments acknowledging that the proposed financial documentation would be too burdensome, particularly for small suppliers. Additionally, the final rule (72 FR 18037) stated that in order to obtain a sufficient amount of information about each bidding entity, while minimizing the burden on both bidding entities and the bid evaluation process, CMS would require, for the initial round of competition (what is referred to as the Original Round 1), bidding entities to submit certain schedules from its tax returns, a copy of the 10K filing report from the immediate 3 years immediately prior to the date on which the bid is submitted (if the

supplier is publicly traded), certain specified financial statement reports such as cash flow statements, and a copy of its current credit report with a numerical credit score and/or rating, which must have been completed within 90 days prior to the date in which the supplier submits its bid and must have been prepared by one of the following: Experian, Equifax, or TransUnion.

The covered documents described in the 2007 final rule were also outlined in the Original Round 1 RFB in accordance with 42 CFR 414.414(d), which states that each bidding entity must submit along with its bid⁹⁵ the applicable covered documents specified in the RFB. For all subsequent rounds after the Original Round 1 (Round 1 Rebid through Round 2021), the covered documents were specified in the RFB for each applicable round, which included the tax return, income statement, balance sheet, statement of cash flows, and a credit report with a numerical credit score and/or rating.

On January 16, 2009 we published in the **Federal Register** an interim final rule titled “Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)” (hereafter referred to as the “2009 interim final rule”) (74 FR 2876) that codified the process for reviewing covered documents aforementioned in § 414.414(d)(2).

Additionally, the 2006 proposed rule (71 FR 25675) and the 2007 final rule (72 FR 18037) stated that applying financial standards would assist CMS in assessing the expected quality of bidding entities, estimating the total potential capacity of winning contract suppliers, and ensuring that winning contract suppliers are able to continue to serve market demand for the duration of their contracts. We also stated that we would generally require that bidding entities submit the same types of information for subsequent competitions, but we might choose to add or delete specific document requests as we gather experience on what financial information most accurately predicts whether a supplier is financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period (72 FR 18037).

2. Current Issues

CMS is soliciting comments on a proposal to reduce the number of covered documents that bidding entities are required to submit during the bid window and modify how CMS will evaluate and determine the financial standards for each bidding entity, while still ensuring that a bidder offered a contract is financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. We believe a bidding entity's credit score is an up-to-date, reliable, and sufficient measure of the entity's ability to serve market demand for the duration of the contract performance period because data from Round 2021 shows that only 1.7 percent of bidding entities' Tax Identification Numbers (TINs) had a lower credit score, and 21.1 percent of those bidding entities' TINs no longer had an active location (otherwise known as a Provider Transaction Access Number (PTAN)) as of December 28, 2023—the specifics for how these percentages were calculated are described later in this section. This proposal would also align with CMS's focus on continuous process improvement and increase operational and policy efficiency and effectiveness for all aspects of the DMEPOS CBP, while ensuring the integrity of the program is not compromised.

Specifically, CMS is soliciting comments on a proposal to reduce the burden of submitting financial documentation from bidding entities by no longer requiring the submission of a tax return extract, income statement, balance sheet, and statement of cash flows. However, CMS would still require bidding entities to submit a credit report with a numerical credit score or rating from one of the approved credit reporting agencies during the bid window. This proposal will significantly reduce the burden on bidding entities as they will only be required to submit a credit report with a numerical credit score or rating.

To further clarify, CMS is soliciting comments on a proposal to require a bidding entity submit a business credit report with a numerical credit score or rating. However, there may be instances where the bidding entity does not have a business credit report with a numerical credit score or rating if the entity has not been in operation long enough to generate a numerical score or rating. Bidding entities that are unable to generate a credit report with a numerical credit score or rating would be required to submit a business credit report showing no data or insufficient information to generate a credit score, in

addition to a personal credit report with a numerical credit score or rating from the supplier's Authorized Official or Delegated Official listed in CMS' PECOS. If the individual's name on the credit report is not an Authorized Official or Delegated Official listed in PECOS, CMS will deem the personal credit report with a numerical credit score or rating unacceptable, and the supplier will not be eligible for a DMEPOS CBP supplier contract.

Commonly owned and/or commonly controlled bidding entities are prohibited from competing against themselves when submitting bids in the same competition. Therefore, when registration opens, commonly owned and/or commonly controlled bidding entities must register one time with a primary Provider Transaction Access Number (PTAN) which designates the primary location in the bidding system and identifies the entity responsible party for all contractual requirements (that is, the bidding entity). When the bid window opens, the bidding entity must submit one bid that includes all commonly owned and/or commonly controlled locations that would furnish the lead item and all non-lead items in the same competition. The legal business name (LBN) for the primary location will auto-populate in the bidding system on the Business Organization section of Form A. This LBN must be the same LBN on your bid surety bond(s). If awarded a contract, CMS will contract with the legal business entity identified by the LBN for the primary location.

Given the longstanding policy as specified in the Request for Bid Instructions, commonly owned and/or commonly controlled supplier organizations that submit separate bids for the same competition will have their bids for the competition disqualified.

Similarly, as specified in the Request for Bid Instructions the bidding entity must attest in the bidding system that it is submitting one bid that includes all commonly owned and/or commonly controlled locations, and that it will furnish the lead item and all non-lead items in the same competition.

The bidding entity must upload a copy of its business' credit report showing a numerical credit score or rating, the entity's name, the entity's name, and the date that the credit report was prepared not earlier than 90 calendar days prior to the opening of the bid window in a form and manner specified by CMS. If the numerical credit score or rating is generated separately from the credit report, the bidding entity's name and the date it was prepared must be shown on both

⁹⁵ Bid means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.

the credit report and the numerical credit score or rating.

Bidding entities that are unable to generate either a credit report with a numerical credit score or rating would be required to submit a business credit report showing no data or insufficient information to generate a credit score or rating, and would be further required to submit a personal credit report with a numerical credit score or rating from the supplier's Authorized Official or Delegated Official listed in CMS' PECOS.

This proposal would also reduce the resources needed to review the submissions of covered documents and will streamline the evaluation of financial standards, while ensuring that the entities that are awarded a contract are financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. In addition, bidding entities may have improved opportunity to receive a contract offer because they will no longer be disqualified due to errors in their submitted financial statements and tax return extracts, which would disqualify a bidding entity in previous rounds.

CMS analyzed all credit reports with a numerical credit score or rating from bidding entities that submitted a complete bid⁹⁶ in the most recent round of the DMEPOS CBP (Round 2021), as well as Medicare supplier enrollment data, that indicated if a bidding entity's credit report with a numerical credit score or rating is sufficient in determining the financial stability of a bidding entity and if they can fulfill its contractual obligations for the duration of the contract performance period. Specifically, CMS first determined

which bidding entities submitted a complete bid for all product categories competed in Round 2021 (the analysis was not limited to the bidding entities that submitted a complete bid for the OTS Back Brace and OTS Knee Brace product categories that were included in Round 2021) to determine how many bidding entities (identified by TIN) were included on the submission of a complete bid. CMS identified 1,153 bidding entities' TINs and first determined how many of them were still in business as of December 28, 2023, by utilizing data from PECOS.

CMS found that 88.2 percent (1,017 of 1,153) of bidding entities' TINs still had at least one PTAN as of December 28, 2023. Because the Round 2021 bid window was open from July 16, 2019, through September 18, 2019, this means that 88.2 percent of the 1,153 Round 2021 bidding entities had at least one PTAN that was still active/enrolled as a Medicare-enrolled supplier more than 4 years later, supporting the fact that most DMEPOS CBP suppliers are able to stay in business for the duration of a DMEPOS CBP supplier contract performance period which cannot exceed 3 years. CMS would like to note that this timeframe was during the COVID-19 pandemic indicating that companies that submit a bid to participate in the DMEPOS CBP appear to typically be financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period as most were able to stay in business during/after the pandemic.

Additionally, CMS analyzed the numerical credit score and/or rating on the credit report for each bidding entity's TIN to determine where the majority of bidding entities fell within CMS' five-tier credit scoring system. Table 49 outlines the 5-tier credit scoring system, and table 50 provides a description of each business credit report, which were both included in the

Round 2021 Financial Scoring Methodology Fact Sheet. Table 49 (Credit Report Scoring List) contains a list of credit reports and credit scores or ratings, as well as the associated tiers and scoring. All bidding entities were required to submit a credit report with a numerical credit score and/or rating on the Credit Report Scoring List and depending on the bidding entity's credit score or rating, the bidding entity fell within a specific tier and received a correlating score of either 4, 8, 12, 16, or 20 points, where a score of 4 is the worst and 20 is the best. Historically, a bidding entity could receive a maximum score of 20 points from its credit report with a numerical credit score or rating and the remaining 80 points (equating to 100 total points) from its tax return extract, income statement, balance sheet, and statement of cash flows, which will no longer be applicable in future rounds of the DMEPOS CBP per this proposal. Specifically, the remaining 80 points were determined by computing each standard accounting ratio for each bidding entity and arraying the bidding entities from the best to worst ratio. Bidding entities in the bottom 10 percent of the array for a specific ratio received a score of 1 (worst) and suppliers in the top 10 percent of the array for a specific ratio received a score of 7.6 or 9.6 (best). The remaining bidding entities' (that is, those falling in-between the top and bottom 10 percent) scores were prorated between 1 and 7.6/9.6. Of the 10 standard accounting ratios, eight have a maximum score of 7.6, while two have a maximum score of 9.6. This information was contained in the Round 2021 Financial Scoring Methodology Fact Sheet.

Table 49 includes a detailed description of each business credit report to help suppliers understand the difference between the business credit reports.

⁹⁶ A complete bid is defined as a supplier submitting an approved Form A and a certified Form B in the DMEPOS Bidding System, as well as uploading at least one bid surety bond and at least one of the required financial documents in the DMEPOS CBP's secure portal, by the close of the window.

TABLE 49: CREDIT REPORT SCORING LIST

Credit Report Name	Tiers and Scoring				
	20	16	12	8	4
Business Credit Reports					
Equifax - Business Payment Index	100-90	89-80	79-60	59-40	39-1
Equifax - Business Credit Risk Score	992-697	696-649	648-575	574-492	491-101
Equifax - Business Delinquency Score	662-477	476-446	445-400	399-347	346-101
Equifax - Business Failure Risk Score	1610-1488	1487-1366	1365-1244	1243-1122	1121-1000
Experian - Intelliscore Credit Ranking Score/Business Credit Score	100-76	75-51	50-26	25-11	10-1
Experian - Financial Stability Risk Class	1	2	3	4	5
Dun & Bradstreet - Delinquency Predictor Risk Class	1	2	3	4	5
Dun & Bradstreet - Commercial Credit Score	670-580	579-530	529-481	480-453	452-101
Dun & Bradstreet - Supplier Evaluation Risk Rating	1-2	3-4	5-6	7-8	9
Dun & Bradstreet - Paydex	100-80	79-62	61-46	45-32	31-1
Dun & Bradstreet - Financial Stress Class	1	2	3	4	5
Standard & Poor's	AAA	A	BBB	BB	CC
	AA			B	C
				CCC	D
Personal Credit Reports					
Experian - Plus Score	830-721	720-681	680-630	629-480	479-330
Equifax - Score	850-760	759-725	724-660	659-560	559-280
Transunion - Score	850-781	780-661	660-601	600-501	500-300
FICO SCORE - Experian, Equifax, TransUnion	850-781	780-661	660-601	600-501	500-300
Vantage	850-781	780-661	660-601	600-501	500-300

TABLE 50: BUSINESS CREDIT REPORTS WITH DETAILED INFORMATION ON SCORING OR RATING

Approved Credit Reporting Agency	Acceptable Credit Score or Rating	Detailed Description of the Credit Score or Rating
Equifax	Business Payment Index	The Payment Index is a dollar-weighted indicator of a business's payment performance based on the most recently reported financial and non-financial payment experiences.
Equifax	Business Credit Risk Score	The Business Credit Risk Score predicts the likelihood of a business incurring greater than 90 days severe delinquency or charge-off within a 12-month period.
Equifax	Business Delinquency Score	The Business Delinquency Score predicts the likelihood of severe delinquency (91 days or greater), charge-off or bankruptcy within the next 12 months.
Equifax	Business Failure Risk Score	The Business Failure Score predicts the likelihood of business failure through either formal or informal bankruptcy within the next 12 months.
Source: www.equifax.com		
Experian	Intelliscore Credit Ranking Score/Business Credit Score	The Intelliscore Credit Ranking Score predicts the likelihood of delinquency within the next 12 months. Predicts seriously derogatory payment behavior.
Experian	Financial Stability Risk Class	The Financial Stability Risk Class quickly identifies the highest risk businesses and avoid bankruptcy risk and accounts likely to default.
Source: www.experian.com		
Dun & Bradstreet	Delinquency Predictor Risk Class	The Delinquency Predictor Risk Class predicts the likelihood that a company will pay its bills late or on time over the next 12 months.
Dun & Bradstreet	Commercial Credit Score	The Commercial Credit Score predicts the likelihood of an account becoming severely delinquent within the next 12 months.
Dun & Bradstreet	Supplier Evaluation Risk Rating	The Supplier Evaluation Risk Rating predicts the likelihood that a supplier will cease business operations or become inactive over the next 12 months-predicts whether the business will deliver goods and services as promised.
Dun & Bradstreet	Paydex	The Paydex score indicates how quickly a company pays its bills based on the payment experiences in the D&B credit file.
Dun & Bradstreet	Financial Stress Class	The Financial Stress Class predicts the likelihood that a business will experience financial distress or failure over the next 12 months.
Source: www.dnb.com		
Standard & Poor's	S&P Ratings	An S&P credit rating is a forward looking opinion on the creditworthiness of an obligor to meet its overall financial commitments, or financial commitments with respect to specific issues/programs.
Source: www.standardandpoors.com		

The Round 2021 data showed that only 1.7 percent (19 out of 1,133) of suppliers' TINs received a credit score or rating of 8 or lower. Please note that CMS was not able to calculate a score for 20 bidding entity TINs (1,153 – 1,133), mainly due to the following reasons:

- The credit report submitted was not for the entity that submitted the bid.
- There was no date on the credit report indicating when it was generated (credit reports were required to be generated no earlier than 90 calendar days prior to the opening of the bid window).

- A bidding entity that filled a tax return (Form 1120) as a regular "C" corporation submitted a personal credit report instead of a business credit—all were requirements outlined in the Round 2021 RFB.

CMS analyzed the 19 suppliers' TINs that received a score of 8 or lower aforementioned and found that 21.1 percent (4 of the 19) of those bidding entities' TINs did not have an active PTAN as of December 28, 2023, supporting our experience that there is a strong correlation between a bidding entity that has a poor credit score and a supplier no longer being enrolled with Medicare.

CMS is soliciting comments on a proposal to continue requiring each bidding entity to submit a credit report with a numerical credit score or rating that is on the CMS Credit Report Scoring List. This list cannot be finalized until closer to when the bid window opens as credit reporting agencies occasionally update the names of their credit reports, as well as the credit score or rating ranges, so CMS is also soliciting comments on a proposal to include the list that is applicable for each round in the round-specific RFB or a Financial Scoring Methodology Fact Sheet, so bidding entities have plenty of time to obtain the applicable information and submit it prior to the close of the bid window.

CMS is also soliciting comments on a proposal to continue using the same 5-tier scoring system, so bidding entities will continue to receive a score of 4, 8, 12, 16, or 20 for their credit report with a numerical credit score or rating as it was successful in Round 2021 per the aforementioned data. Because the credit report with a numerical credit score or rating will be the only covered document submitted, CMS is soliciting comments on a proposal to deem a bidding entity that receives a minimum score of 12 or higher as passing—meets financial sustainability threshold and be financially eligible for a potential contract offer. We believe that a score of

12 or above would be indicative of the bidding entity being financially stable enough to furnish DMEPOS items during the contract performance period. If deemed as "passing," the bidding entity will continue to be evaluated for a potential contract offer. Because the Credit Report Scoring List as well as the tier and scoring information will be published prior to the bid window opening, bidding entities will be able to determine if they meet CMS's financial standards prior to submitting its bid(s).

Furthermore, CMS is soliciting comments on a proposal to no longer use a bidding entity's financial score to assist in determining the capacity to assign to each contract supplier to meet projected beneficiary demand. Specifically, CMS has historically used the bidding entity's financial score, as well as a few other factors, to determine if it can provide more than what it has historically provided to beneficiaries—the details of this process are outlined in the "Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP" proposal where CMS is proposing to use a methodology to establish the target number of contracts to award in each competition, so the financial score is no longer applicable for this process.

Lastly, CMS has historically utilized a bidding entity's tax return extract to determine if the entity is a small supplier and has attempted to have at least 30 percent of contract suppliers be small suppliers in each competition to align with section 1847(b)(6)(D) of the Act. For competitive bidding purposes, a small supplier is a supplier that generates gross revenue of \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue. However, because CMS is proposing to no longer require the submission of the tax return extract and the gross revenue is typically not shown on a credit report, CMS is soliciting comments on a proposal to add a field in the bidding system requiring the bidding entity included on the bid have a gross revenue that is under the small supplier threshold. Additionally, before a bidding entity submits its bid(s) in the bidding system, the entity will be required to attest in the bidding system that the information entered into the bidding system is true, correct, and complete—just as bidding entities have done in prior rounds. All bidding entities will also continue to be presented with the "Penalties for Falsifying Information" in the bidding system prior to submitting bid(s).

CMS intends to review Medicare fee-for-service claims data for bidding entities that indicate in the DMEPOS

Bidding System that they are a small supplier to confirm accuracy. Bidding entities that falsify the small supplier status in the bidding system may be prohibited from participating in the DMEPOS CBP for both the current and the next round of the program in accordance with 42 CFR

414.412(g)(4)(i). Additionally, bidding entities that falsify the small supplier status will be referred to the Office of Inspector General and Department of Justice for further investigation.

3. Provisions of the Proposed Regulation

a. Required Covered Documents

CMS is proposing that each bidding entity submit a business credit report with a numerical credit score or rating, unless the bidding entity does not have a business credit report with a numerical credit score or rating because the entity has not been in operation long enough to generate a numerical score or rating. Bidding entities that are unable to generate a credit report with a numerical credit score or rating would be required to submit a business credit report showing no data or insufficient information to generate a credit score or rating, in addition to a personal credit report with a numerical credit score or rating from the bidding entity's Authorized Official or Delegated Official listed in CMS' PECOS.

The bidding entity must upload a copy of its business' credit report showing a numerical credit score or rating, the bidding entity's name, and the date that the credit report was prepared no earlier than 90 calendar days prior to the opening of the bid window. If the numerical credit score or rating is generated separately from the credit report, the bidding entity's name and the date it was prepared must be shown on the credit report and included with the numerical credit score or rating. We are soliciting comments on this proposal.

b. Financial Scoring Methodology

CMS is proposing to continue publishing a Credit Report Scoring List and utilize the same five-tier credit report scoring system used in prior rounds of the DMEPOS CBP. The report will be published in the round specific RFB and/or a fact sheet prior to the opening of the bid window, and will contain the same credit reports with numerical scores or ratings, unless: a credit reporting agency discontinues, changes the name of a credit report, and/or revises the numerical score/rating ranges.

CMS is proposing to continue using the 4, 8, 12, 16, or 20 scoring system

when evaluating a bidding entity's credit report with a numerical credit score or rating. CMS is proposing to deem a bidding entity that receives a minimum score of 12 or higher as passing—meets financial sustainability threshold. If deemed as passing, the bidding entity will continue to be evaluated for a potential contract offer.

CMS is proposing to no longer use a bidding entity's financial score to assist in determining the capacity to assign to each contract supplier to meet projected beneficiary demand.

CMS is proposing to add a field in the bidding system requiring the bidding entity to verify that all the bidding entities included on the bid has a gross revenue that is under the small supplier threshold. We are soliciting comments on this proposal.

I. Revising the CDRD Evaluation and Notification Process for the DMEPOS CBP

1. Background

If a bidding entity submits at least one covered document by the CDRD and one or more covered documents are missing, per section 1847(a)(1)(F)(i)(I) of the Act the Secretary is required to notify the bidding entity no later than 45 days (in the first round of competition acquisition program as described in subparagraph (B)(i)(I)) or 90 days (in subsequent rounds of such programs) after the CDRD of any missing covered document(s).

Section 1847(a)(1)(F)(i)(II) of the Act specifies that the Secretary may not reject the bid submission on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidding entity are submitted to the Secretary no later than 10 business days after the date of such notice. Per the limitations of this process in section 1847(a)(1)(F)(iii)(I) through (IV) of the Act, section 1847(a)(1)(F)(i)(I) and (II) of the Act— (1) applies only to the timely submission of covered documents; (2) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether the documents meet applicable requirements; (3) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II) of section 1847(a)(1)(F) of the Act; and (4) shall not be construed as permitting a bidding entity to change bidding amounts or to make other changes in a bid submission.

Per section 1847(a)(1)(F)(ii)(I) and (II) of the Act, the CDRD is the later of the date that is 30 days before the final date

specified by the Secretary for submission of bids under the program or the date that is 30 days after the first date specified by the Secretary for submission of bids under the program.

The 2009 interim final rule codified the CDRD process, which is outlined in 42 CFR 414.414(d)(2) (74 FR 2876 through 2877).

2. Current Issues

Since the inception of the DMEPOS CBP, within either 45 (for Round 1 bids) or 90 days (for subsequent round bids) after the CDRD, CMS has notified bidding entities that submitted at least one covered document by the CDRD, if a covered document was missing by the CDRD and by the close of the bid window. The first step has been identifying the universe of bidding entities that submitted a covered document by the CDRD. The next step has been to determine if each bidding entity with a complete bid has any missing documents covered by the CDRD and the closing of the bid window. If a covered document is identified as missing by the CDRD, CMS then determines if the covered document was received or not by the close of the bid window. Once the analysis is completed, CMS has communicated its findings to the applicable bidding entity within 45 or 90 days after the CDRD, as applicable. CMS specifies in each bidding entity's notification, to the extent applicable, if: (1) a covered document(s) was missing by the CDRD and was still missing by the close of the bid window, (2) a covered document(s) was missing by the CDRD date but was received by the close of the bid window, (3) covered documents were missing by the CDRD but at least one of the missing covered documents was received by the close of the bid window while the other covered document(s) was still missing by the close of the bid window, or (4) no covered document(s) was missing by the CDRD.

CMS is proposing to streamline the evaluation and notification processes by only informing bidding entities if a covered document was missing by the close of the bid window. Each bidding entity would receive a notification stating if: (1) a covered document(s) was missing by the close of the bid window; or (2) no covered document(s) was missing by the close of the bid window. CMS believes that this proposal aligns with the intent of statute as bidding entities would continue to be notified of any missing covered documents (as long as they submit at least one covered document by the CDRD) and would continue to be able to submit any

missing covered documents within 10 business days of receiving the notification.

This proposal would also reduce CMS workload in determining if/when a covered document is missing for bidding entities that submitted at least one covered document by the CDRD. Specifically, CMS is proposing to identify the universe of bidding entities that submitted at least one covered document by the CDRD and then determines if they have a missing covered document(s) by the close of the bid window. CMS would notify bidding entities if they have missing covered documents or if all covered documents were submitted, so CMS will only have to send two different types of notifications compared to the four different notifications previously mentioned. Additionally, due to the simplification of the notifications, bidding entities would have an easier time understanding which covered documents they may need to submit in response to their notification. We are soliciting comments on this proposal.

3. Provisions of the Proposed Regulation

CMS is proposing to streamline the evaluation and notification processes for missing covered document(s). Under this proposal, CMS would no longer evaluate if a bidding entity was missing a covered document(s) by the CDRD and by the close of the bid window, and would only determine if a bidding entity had a missing covered document by the close of the bid window. Once the evaluation is completed, CMS is proposing to continue notifying bidding entities, within 90 days of the CDRD, of the specific covered document(s) that was missing or provide confirmation that all applicable covered documents had been received by the close of the bid window. Bidding entities would continue to have 10 business days from receiving their notification to submit the missing covered document(s). We are soliciting comments on this proposal.

J. Bid Surety Bond Review Process

1. Background

Section 1847(a)(1)(G) of the Act, as added by section 522(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA), requires a bid surety bond for bidders. We believe that a bid surety bond would help address the fact that the bids submitted under the DMEPOS CBP are not binding, which can encourage the practice of bidders submitting “low-ball” bids. Requiring a bid surety bond was also believed to reduce the number of bad actors submitting bids in the

DMEPOS CBP, while imposing a penalty for a bidder that doesn't accept a contract that they won.

If a bidder is offered a contract for a competition and its bid is at or below the median composite bid rate for all bidders included in the calculation of the SPA, and it does not accept the contract offer, the bidder's bid surety bond would be forfeited for that CBA. Bidders that accepted the contract offer, or those bids that are above the median composite bid rate, would have the bid surety bond liability returned.

In 2016, CMS published 81 FR 77966 which finalized the regulations at 42 CFR 414.412(g) for setting the requirements for bid surety bonds. Additionally, CMS is proposing to correct a technical error in 42 CFR 414.412(g) that happened as a result of a previous paragraph re-designation in 83 FR 57072.

2. Current Issues

This proposal codifies how CMS handles situations where at least one of the bid surety bond requirements outlined in 42 CFR 414.412(g)(2)(i) and (ii) is not properly met after a bidder submits its bid surety bond(s) during the bid window. Specifically, if CMS determines that a bid surety bond requirement is not met, the bidder would be notified by CMS and would be provided with an opportunity to correct the deficiency on the bid surety bond via a bid surety bond rider. A bid surety bond rider is a change or amendment to the original bid surety bond. It is the only legal way of modifying or updating information on a bid surety bond which is still in effect, and it can only be issued by the authorized surety agency that issued the original bid surety bond. Allowing bidders to submit a bid surety bond rider would provide bidders that have a bid surety bond deficiency(s) an opportunity to correct the deficiency(s) instead of the bid(s) for the applicable CBA(s) being disqualified in the early stages of the bid evaluation process. Bids that are disqualified for a bid surety bond deficiency are not included in other bid evaluation processes that are necessary to determine if a bid is eligible for a contract offer.

CMS applied the bid surety bond rider process during bid evaluation for Round 2021 of the DMEPOS CBP, and is now proposing to codify this process in regulation. Additionally, CMS is proposing correcting a technical error in 42 CFR 414.412(g) that happened as a result of a paragraph re-designation in 83 FR 57072.

3. Provisions of the Proposed Regulation

CMS proposes correcting a technical error created in 83 FR 57072 where CMS re-designated paragraphs (e) through (h) as paragraphs (d) through (g), respectively. The re-designated paragraph (g)(3)(ii) still contained a reference to the paragraph (h)(3)(i), which, with the re-designation, was deleted in its entirety. This proposed correction would revise existing paragraph (g)(3)(ii) by removing the reference to "(h)(3)(i)" and replacing it with "(g)(3)(i)". All other parts of paragraph (g)(3)(ii) remain unchanged with this proposal. We are soliciting comments on this proposal.

In 2015, Congress passed section 522(a) of MACRA, which required a bid surety bond for bidders. In 2016, CMS published 81 FR 77967 which finalized the regulations at 42 CFR 414.412(g) for setting the requirements for bid surety bonds. Round 2021 of the DMEPOS CBP was the first round that required bid surety bonds. As a result, CMS reviewed all bids to ensure a bid surety bond was uploaded to the DMEPOS CBP's secure portal by the deadline for bid submission for each CBA in which a bid was submitted, and that it met all bid surety bond requirements outlined in 42 CFR 414.412(g)(2)(i)–(ii). During the Round 2021 bid evaluation, CMS was able to identify bid surety bonds that had deficiencies with the bid surety bond requirements, and allowed certain deficiencies to be corrected via a bid surety bond rider.

Round 2021 had 1,338 bidders and 43 were identified as having at least one bid surety bond with a minimum of one deficiency that was able to be corrected via a bid surety bond rider. These 43 bidders were provided with the opportunity to submit a bid surety bond rider from its surety within a 10-business day timeframe rectifying all deficiencies. Of the 43 bidders, 40 responded within the allotted timeframe; however, only 36 out of the 40 bidders submitted a bid surety bond rider that properly corrected the deficiencies. After successful implementation of the process for Round 2021, CMS is proposing to include this process in all future rounds of the program.

Each bid surety bond requirement, described in 42 CFR 414.412(g)(2)(i)–(ii), is listed later in this section followed by an example(s) of the type of deficiency that could be corrected by a bid surety bond rider, which is a change or amendment to the original bid surety bond, that can only be issued by the authorized surety, at its discretion, that issued the original bid surety bond:

- The name of the bidder as the principal/obligor: If a bidder submits a bid surety bond that contains a name of a different entity other than the Legal Business Name entered in the Business Organization section of Form A in the DMEPOS Bidding System, for example using its "doing business as" name or the name is missing the "LLC" at the end, then the error can be corrected by a bid surety bond rider.

- The name and the National Association of Insurance Commissioners (NAIC) number of the authorized surety: If a bidder submits a bid surety bond with a missing or illegible name or NAIC number, or the NAIC number does not match the name on the Treasury Department's list of authorized sureties, these issues can be corrected with a bid surety bond rider.

- CMS as the named obligee: If a bidder submits a bid surety bond without naming CMS as obligee or names another agency or department as obligee, this error can be corrected by a bid surety bond rider.

- The conditions of the bid surety bond as specified in § 414.412(g)(3), which is forfeiture of the bid surety bond language: If a bidder submits a bid surety bond that is missing part or all of the pertinent language on forfeiture of the bid surety bond, then the omission of bid surety bond forfeiture language can be corrected by a bid surety bond rider.

- The CBA covered by the bid surety bond: If a bidder submits a bid surety bond with an incorrect or missing CBA name, then the CBA name can be corrected by a bid surety bond rider.

- The bid surety bond number: If a bidder submits a bid surety bond with a missing or illegible bid surety bond number, then the bid surety bond number can be corrected by a bid surety bond rider.

- The date of issuance: If a bidder submits a bid surety bond with a missing or illegible date of issuance, then the date of issuance can be corrected by a bid surety bond rider.

- The bid surety bond value of \$50,000.00: If a bidder submits a bid surety bond for a value other than \$50,000.00, then the bid surety bond value can be corrected by a bid surety bond rider.

The following are examples of the type of deficiencies that a bidder may have on its bid surety bonds that cannot be corrected by a bid surety bond rider:

- Late Bid Submissions: CMS will not review any bid surety bonds that are submitted after the deadline for bid submission. The Social Security Act clearly states that bidders must provide "proof of having obtained" a bid surety

bond by the “deadline for bid submission.” Submission of a bid surety bond rider will not rectify a bid(s) from a bidder that is disqualified for having a bid surety bond failure, if the failure was for not submitting a bid surety bond prior to the deadline for bid submission. This would also include a bidder that submitted a document other than a bid surety bond (for example, a Medicare enrollment bond, or a Certificate of Liability Insurance). No notice would be provided to a bidder in this situation.

- **Missing Bid Surety Bonds:** If a bidder submitted bids in two different CBAs, but the bidder uploaded the same bid surety bond for both CBAs, then the bidder will not be notified that there is a deficiency for the bid for the CBA in which the bid surety bond that was never uploaded, as a bid surety bond rider cannot correct the issue of a missing bid surety bond, and the bidder did not provide proof of having a bid surety bond for the one CBA by the deadline for bid submission. For example, this could occur by error, where the bidder accidentally uploaded the same bid surety bond for both CBAs, despite having two bid surety bonds; or this could occur by a mistaken understanding of the bidder that one bid surety bond should be sufficient for both CBAs.

Bidders would be notified by CMS of the deficiency (that is, the incorrect, incomplete, or missing requirement), and would be permitted to obtain the bid surety bond rider within a certain timeframe to submit to CMS in order for its bid(s) to remain eligible for further review during bid evaluation. CMS proposes sending the notification to bidders and having bidders provide the bid surety bond riders via the DMEPOS CBP’s secure portal. CMS will not notify bidders of deficiencies that are not correctable with a bid surety bond rider during this review process.

CMS is proposing to provide bidders with a single, 10-business day timeframe to obtain and submit a bid surety bond rider correcting the deficiencies on the bid surety bond. A 10-business day timeframe was utilized for Round 2021, which provided bidders ample time to obtain a bid surety bond rider from the authorized surety that issued the original bid surety bond and submit the bid surety bond rider via the DMEPOS CBP’s secure portal. Additionally, we anticipate the 10-business day timeframe will run concurrent with other bid evaluation processes, and extending this timeframe would result in some bid evaluation processes being delayed until the bid surety bond rider review process is complete, impacting CMS’s ability to

continue evaluating all bids submitted and ultimately awarding contracts in a timely manner. Lastly, CMS believes that bidders have the resources (for example, fact sheets, bid surety bond template) available, and that it is the responsibility of the bidder to submit a bid surety bond that meets all bid surety bond requirements outlined in 42 CFR 414.412(g)(2)(i)–(ii). For these reasons, CMS believes a single, 10-business day opportunity to rectify the deficiency is sufficient. We are soliciting comments on this proposal.

K. Tribal Exemption From Participating in the DMEPOS CBP

1. Background

There is a special government-to-government relationship between the federal government and federally recognized tribes based on U.S. treaties, laws, Supreme Court decisions, Executive Orders, and the U.S. Constitution. This government-to-government relationship forms the basis for federal health services to American Indians/Alaska Natives (AI/AN) in the U.S. In 1976, the Indian Health Care Improvement Act (IHCA) (Pub. L. 94–437, September 30, 1976) amended the Act to permit payment by Medicare and Medicaid for services provided to AI/ANs in Indian Health Service (IHS) and Tribal health care facilities that meet the applicable requirements. Under this authority, Medicare services may be furnished by IHS operated facilities and programs, and Tribally operated facilities and programs, under Title I or Title V of the Indian Self Determination Education Assistance Act, as amended (ISDEAA) (Pub. L. 93–638, January 4, 1975) to AI/ANs. The IHS healthcare delivery system currently consists of 46 hospitals, with 22 of those hospitals operated by the IHS and 24 of them operated by Tribes under the ISDEAA, as well as 380 health centers, 50 operated by IHS and 417 operated by Tribes under the ISDEAA.

The Act prohibits Medicare payment to non-contract suppliers under the DMEPOS CBP. Specifically, section 1847(b)(6) of the Act states that, “payment shall not be made for items and services described in section 1847(a)(2) furnished by a contractor and for which competition is conducted under this section unless: (i) the contractor has submitted a bid for such items and services under this section; and (ii) the Secretary has awarded a contract to the contractor for such items and services under this section.”

However, section 1862(a)(17) of the Act carves out an exception to this rule. Section 1862(a)(17) of the Act states,

“Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1847(a)) by an entity other than an entity with which the Secretary has entered into a contract under section 1847(b) for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary.”

2. Current Issues

Tribes that operate health facilities or suppliers under the ISDEAA have approached CMS requesting an exception from the DMEPOS CBP to allow Medicare payment for competitively bid items provided to AI/AN Medicare beneficiaries, who reside in a CBA, but who receive services from an IHS or Tribally operated facility or supplier, which can be located 60 or 90 minutes outside the CBA. Many of these AI/AN Medicare beneficiaries receive primary care services at a Tribally operated facility, and, as a result of this visit, might be provided DMEPOS by the facility or a Tribally operated supplier. Without an exception, the IHS or Tribally operated facility or supplier would not be paid by Medicare when providing competitively bid DMEPOS to eligible AI/AN Medicare beneficiaries during an active round of the DMEPOS CBP.

In addition, under the Indian Health Care Improvement Act (IHCA), AI/ANs who are eligible for services from the IHS, in general do not pay coinsurance for DMEPOS they receive from an IHS supplier or facility. However, under an active round of the DMEPOS CBP, AI/AN Medicare beneficiaries residing in a CBA must receive DMEPOS from a competitive bidding contract supplier in their CBA and pay a 20 percent coinsurance, even in cases where they receive care at a Tribally operated facility outside their CBA. This creates added expenses for AI/AN Medicare beneficiaries.

3. Provisions of the Proposed Regulation

CMS is proposing to use the authority at section 1862(a)(17) of the Act to add an exception to § 414.408(e)(2) that would allow Medicare payment to IHS or Tribally operated facilities and suppliers that furnish competitively bid items and services to AI/AN Medicare beneficiaries who reside in a CBA so that the AI/AN Medicare beneficiaries can retain the benefits described

previously when receiving DMEPOS items and services from a Tribal supplier. We are soliciting comments on this proposal.

L. Addition of a Termination Clause for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) Supplier Contracts

1. Background

As previously discussed, an important benefit of the DMEPOS CBP is that it ensures access to covered DMEPOS items and services. Current regulations at 42 CFR 414.422 establishing the terms of each DMEPOS CBP contract state that contract suppliers must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier. CMS implemented these regulations pursuant to section 1847(b)(3)(A) of the Act, which states that the Secretary may specify the terms and conditions of a DMEPOS CBP contract. In the 2006 proposed rule (71 FR 25682), CMS proposed adding a unilateral contract termination for convenience clause to the DMEPOS CBP supplier contracts. After receiving multiple public comments challenging the termination for convenience clause, per the 2007 final rule (72 FR 18054–18055), CMS decided not to finalize the proposal.

2. Current Issues

Since the inception of the DMEPOS CBP, CMS has never verified an instance where all contract suppliers for a competition were not able to meet beneficiary demand for the competition, even during a PHE. For example, after the Secretary of HHS declared PHEs after major hurricanes, contract suppliers were able to replace damaged DMEPOS and furnish competitively bid DMEPOS items to beneficiaries without any access concerns. CMS believes this can be attributed to the fact that not all contract suppliers for a CBA are physically located within the impacted CBA. Also, Medicare requires Medicare-enrolled DMEPOS suppliers to “have a contingency plan that enables it to respond to emergencies and disasters, or to have arrangements with alternative suppliers in the event that the supplier cannot service its own customers as a result of an emergency or disaster” (see section 1.F of the CMS DMEPOS Quality Standards). CMS has experienced that contract suppliers are prepared to promptly resume operations, and remain in compliance with the terms of the DMEPOS CBP supplier contract,

without a need for any contract action by CMS. Additionally, there is an already established network of agencies and organizations at the federal, state, and local levels that are integral in responding to the immediate needs, including DMEPOS needs, during a PHE. For instance, CMS works closely with HHS’s Administration for Strategic Preparedness and Response (ASPR) that leads the nation’s medical and public health preparedness for, response to, and recovery from disasters and other PHEs.

Nevertheless, we are concerned that, in the event of a PHE, contract suppliers may be unable to fulfill their obligations under DMEPOS CBP supplier contracts to furnish certain required items and services to beneficiaries in CBAs or defined area(s) within CBAs specified in the contracts and affected by the PHE (the PHE-impacted area). In the event that CMS determines that, due to a PHE, contract suppliers are unable to furnish items and services to beneficiaries in a PHE-impacted area specified in their DMEPOS CBP contracts, we believe it is prudent for CMS to have the authority to unilaterally terminate or modify each applicable contract to exclude the requirement to furnish such items and services in the PHE-impacted area from the scope of the DMEPOS CBP. If the items and services in the PHE-impacted area to be removed from the DMEPOS CBP encompasses all competitions referenced in a DMEPOS CBP contract, CMS would unilaterally terminate the contract supplier’s entire contract. If the items and services in the PHE-impacted area to be removed from the DMEPOS CBP encompass only a portion of the items and services and areas referenced in a DMEPOS CBP supplier contract, CMS would unilaterally modify the contract to exclude the requirement to furnish the applicable items and services in the PHE-impacted area. Upon modification, the contract supplier would no longer be obligated under the terms of the contract to furnish the specified items and services in the PHE-impacted area, and CMS would no longer provide payment under the contract for furnishing those items and services in that area. Depending on the PHE, such area may be a specific CBA or a defined area within a CBA. A DMEPOS CBP supplier contract modified to exclude the requirement to furnish certain items and services in the PHE-impacted area would continue to remain in effect for all other items and services and all other geographic areas that are within the scope of the contract. Upon the termination and/or modification of each DMEPOS CBP

supplier contract impacted by the PHE, any Medicare enrolled DMEPOS supplier would be able to furnish the applicable items and services to Medicare beneficiaries in the PHE-impacted area.

CMS would reserve the right to unilaterally terminate or modify every DMEPOS CBP supplier contract impacted by a PHE in accordance with the above if the following conditions are met: (1) the Secretary of HHS declares a PHE, (2) CMS determines the PHE has created an access concern for beneficiaries receiving items and services under the DMEPOS CBP in certain CBAs or defined area(s) within CBAs, (3) CMS determines that awarding additional CBP contracts, per 42 CFR 414.414(i), would not address the access concerns, and (4) CMS determines terminating or modifying each impacted DMEPOS CBP supplier contract to exclude those specific areas from the DMEPOS CBP would alleviate access concerns.

To determine whether or not a PHE has created an access concern, CMS would review information obtained directly from the contract supplier(s) impacted by a PHE, along with data obtained through CMS’s monitoring system (complaints, claims data, beneficiary health outcomes, assignment rates, etc.) and from other agencies and organizations at the federal, state, and local levels. CMS would continue to remain in communication with affected contract suppliers throughout a PHE. CMS would share all relevant information from contract suppliers with applicable emergency response partners to aid in the response efforts. We would also be analyzing the information to determine the scope and length of the challenges being experienced to assess whether it is necessary to terminate an entire DMEPOS CBP supplier contract, terminate a competition(s), or terminate a defined area(s) within a CBA. For example, if the Secretary of HHS declares a PHE due to a pandemic and the President of the United States enacts the Defense Production Act to assist with furnishing essential medical supplies, CMS would communicate with contract suppliers to determine if they are able to continue furnishing the competitively bid DMEPOS item to beneficiaries in the CBA under existing conditions. The information and data obtained from contract suppliers would be combined with relevant information gathered from other agencies and organizations at the federal, state, and local levels that are integral in responding to the PHE. We are soliciting comments on this proposal.

In a form and manner to be determined by CMS, CMS would announce the exclusion of the PHE-impacted area from the scope of the DMEPOS CBP to all applicable contract suppliers and would further notify each applicable contract supplier if the DMEPOS CBP supplier's contract, based on this announcement, will be terminated or unilaterally modified.

Any termination or modification made in accordance with this proposal would remain in effect for the remainder of the DMEPOS CBP supplier contract term, even if the PHE ends before the contract's expiration date.

CMS would apply a high degree of prudence when making an informed decision to terminate and/or modify a DMEPOS CBP supplier contract to exclude areas impacted by a PHE. CMS would not consider a situation that does not meet the qualifying criteria previously mentioned. Even if a PHE meets the qualifying criteria, CMS would not terminate and/or modify a DMEPOS CBP supplier contract if the body of evidence and information determines that there is sufficient capacity from remaining contract suppliers, or if CMS is able to award additional contracts to meet the existing market demands for the competition(s) or defined area(s) within a CBA. For example, if most contract suppliers for a competition say that they are unable to furnish an item to beneficiaries, but there are at least two contract suppliers that provide evidence that they can meet the demand for the competition, CMS may decide that there is sufficient capacity remaining from a contract supplier. We are soliciting comments on this proposal.

3. Provisions of the Proposed Regulation

If CMS determines that due to a PHE, contract suppliers are unable to furnish certain items and services to beneficiaries in certain areas impacted by a PHE (PHE-impacted area) as required under their respective DMEPOS CBP supplier contracts, CMS is proposing in § 414.422 to have the option to unilaterally terminate or modify each applicable DMEPOS CBP supplier contract to allow any Medicare enrolled DMEPOS supplier to furnish the applicable items and services to Medicare beneficiaries in the PHE-impacted area. Depending on the geographic extent of the PHE, a PHE-impacted area may refer to entire CBA(s) or only certain areas within a CBA.

If the items and services in the PHE-impacted area identified encompass all competitions referenced a DMEPOS CBP supplier contract, CMS is proposing in

§ 414.422 to unilaterally terminate the DMEPOS CBP supplier contract.

If the items and services in the PHE-impacted area identified encompass only a portion of the items and services and geographic areas referenced in a DMEPOS CBP supplier contract, CMS is proposing in § 414.422 to unilaterally modify the DMEPOS CBP supplier contract to remove the contract supplier's obligation to furnish specified items and services in the PHE-impacted area, as well as CMS's obligation to pay for those items and services under the DMEPOS CBP supplier contract.

After termination and/or modification of all applicable DMEPOS CBP supplier contracts, CMS is proposing in § 414.422 to revert back to the general fee-for-service program requirements set forth in 42 CFR part 414 Subpart D for the applicable competition(s) or defined area(s) within a CBA. As a reminder, fee-for-service (Medicare enrolled) DMEPOS suppliers are not required to furnish DMEPOS to beneficiaries in the CBA, nor are they required to accept assignment, unless they are already participating suppliers with Medicare. We are soliciting comments on this proposal.

CMS is proposing in § 414.422 to have the option to remove items and services furnished in a PHE-impacted areas from the DMEPOS CBP when all of the following qualifying criteria are met: (1) the Secretary declares a PHE; (2) CMS determines that verifiable evidence exists of a DMEPOS access problem for beneficiaries for a certain competition or defined area(s) within the competition's CBA; (3) CMS determines that awarding additional DMEPOS CBP supplier contracts, per § 414.414(i), would not address the access concerns; and (4) CMS determines terminating or modifying each impacted DMEPOS CBP supplier contract to exclude certain competition(s) or defined area(s) within the competition's CBA from the DMEPOS CBP would alleviate access concerns. We are soliciting comments on this proposal.

M. Technical Change to § 414.408(h)(8)

In the 2007 final rule we added § 414.408(h)(7), which set the payment amounts for rented DME requiring frequent and substantial servicing (72 FR 18032). We added § 414.408(h)(7)(i), which referred to paragraph (h)(7)(ii) of this section. Subsequently, we published in the **Federal Register** a final rule in 2011 titled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" (75 FR 73170). In this rule we added paragraph § 414.408(h)(2). As a result of this

addition, what used to be § 414.408(h)(7), became § 414.408(h)(8). However, § 414.408(h)(8)(i) was inadvertently not updated to refer to paragraph (h)(8)(ii), and it still refers to paragraph (h)(7)(ii). We are therefore making a technical change to the regulation text at § 414.408(h)(8)(i) so that it will refer to paragraph (h)(8)(ii) instead of paragraph (h)(7)(ii). We are soliciting comments on this proposal.

N. Definitions of "Competition" and "Adjusted Fee Schedule Amount" and "Unadjusted Fee Schedule Amount" Under § 414.402

The Medicare fee schedule amounts for enteral nutrition furnished in non-CBAs are adjusted using information from the DMEPOS CBP in accordance with § 414.105. The Medicare fee schedule amounts for DME and medical supplies and OTS orthotics furnished in non-CBAs are adjusted using information from the DMEPOS CBP in accordance with § 414.210(g). The Medicare payment amounts for lymphedema compression treatment items are adjusted using information from the DMEPOS CBP in accordance with § 414.1690. For the purposes of streamlining the language under this subpart, we are proposing to add definitions for "Adjusted fee schedule amount" and "Unadjusted fee schedule amount" under § 414.402. We propose that *Adjusted fee schedule amount* means the payment amount established for the item under Subpart C of this part, with the application of § 414.105; Subpart D of this part, with the application of § 414.210(g); or Subpart Q of this part, with the application of § 414.1690. We propose that *Unadjusted payment amount* means the payment amount established for the item under Subpart C of this part, without the application of § 414.105; Subpart D of this part, without the application of § 414.210(g); or Subpart Q of this part, without the application of § 414.1690.

Similarly, for the purpose of streamlining regulation text, rather than continuing to write out "competitive bidding area and product category combination," we are proposing to add a definition for "Competition" under § 414.402 to read *Competition* means a competitive bidding area and product category combination where bids are submitted by suppliers in an attempt to be awarded contracts for furnishing competitively priced items and services within the product category in the competitive bidding area. The contracts must be recompeted not less often than once every 3 years. We are soliciting comments on this proposal.

VIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

B. Information Collection Requirements (ICRs)

In this HH PPS rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). Failure to submit HH QRP data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year would result

in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. As we noted in the CY 2018 HH PPS final rule (82 FR 52738 through 51740), we believe the reconsideration requirements, and the associated burden would be incurred subsequent to an administrative action. In accordance with the implementing regulations for the PRA (5 CFR 1320.4(a)(2) and (c)), the burden associated with any information collected subsequent to the administrative action is exempt from the requirements of the PRA. We have, however, provided detailed cost burden estimates in section VIII. of this proposed rule. We welcome public comments on the accuracy of the cost estimate assigned to this administrative burden.

1. ICRs for HH QRP

As discussed in section III.D.3. of this proposed rule, we are proposing to remove four items as standardized patient assessment data elements beginning with the CY 2026 HH QRP. The four assessment items proposed for collection are (1) Living Situation, (2) Food Runs Out, (3) Food Doesn't Last, and (4) Utilities as outlined in section III.D.5. of this proposed rule. All elements discussed will be collected at the start of care and resumption of care timepoints. To clarify, home health episodes begin with either a start of care or a resumption of care, corresponding

to admission in other PAC settings. We assumed the Living Situation and Utilities data elements require 0.3 minutes each of clinician time to complete. We assume the Food Runs Out and Food Doesn't Last data elements require 0.15 minutes each of clinician time to complete. Therefore, we estimated that there will be a decrease in clinician burden per OASIS assessment of 0.9 minutes at the start of care and resumption of care. We also propose to remove the patient COVID-19 vaccination item beginning with the CY 2026 HH QRP. This item is collected at the transfer of care, death at home, and discharge assessment timepoints of the OASIS and requires 0.3 minutes of clinician time to complete at each of these time points.

The net effect of these proposals is a decrease in four data elements collected at the start of care one data element at transfer of care, death at home, and discharge for the OASIS implemented on April 1, 2026.

For purposes of calculating the costs associated with the information collection requirements, we obtained median hourly wages for these from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/current/oes_nat.htm). To account for other indirect costs such as overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in table 54.

TABLE 54: U.S. BUREAU OF LABOR STATISTICS' MAY 2024 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefit (100%) (\$/hr)	Adjusted Hourly Wage (\$/hr)
Administrative Services Manager	11-3012	\$52.11	\$52.11	104.22
Registered Nurse (RN)	29-1141	\$45.00	\$45.00	\$90.00
Physical therapists (PT)	29-1123	\$48.57	\$48.57	\$97.14
Speech-Language Pathologists (SLP)	29-1127	\$45.87	\$45.87	\$91.74
Occupational Therapists (OT)	29-1122	\$47.28	\$47.28	\$94.56
Miscellaneous Health Technologists and Technicians	29-2090	\$23.84	\$23.84	\$47.68

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2023 show that the SOC/ROC OASIS is completed by RNs (approximately 75.42 percent of the time), PTs (approximately 23.71 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.87 percent of the time). Based on this analysis, we

estimated a weighted clinician average hourly wage of \$91.72, inclusive of fringe benefits, using the hourly wage data in table 55 $(0.7542 \times \$90.00 + 0.2371 \times \$97.14 + 0.0087 \times \$93.15 = \$91.72)$. Individual providers determine the staffing resources necessary.

For purposes of estimating burden, we compare the item-level burden estimates for the OASIS that will be released on April 1, 2026, to the OASIS that was expected to be implemented as of

January 1, 2027, and finalized in CY 2024 HH PPS final rule (88 FR 77763 through 77768). The first component needed to calculate burden is the total estimated assessments for each year in question. Table 55 shows the total number of OASIS assessments that HHAs completed in CY 2023 at the start of care and resumption of care. It also outlines the estimated assessments that are expected to be collected in 2027 based on a 30 percent increase in

completed assessments required for all
payer data submission requirements for
(CY 2023 assessment total + CY 2023

assessment total * 0.3 = Estimated CY

2027 Assessment total based on all
payer data collection).

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**TABLE 55. START OF CARE/RESUMPTION OF CARE OASIS SUBMISSIONS
BASED ON CY 2023 & CY 2025 ESTIMATED OASIS DATA**

Time Point	CY 2023 OASIS Assessments Completed	Estimated CY 2027 OASIS Assessments Based on All-Payer Data Collection
Start of Care	6,627,912	8,616,286
Resumption of Care	911,245	1,184,618
Transfer of Care	1,818,914	2,364,588
Death at Home	48,398	62,917
Discharge	5,389,311	7,006,104
Total Assessments	14,795,780	19,234,513

The totals from table 55 are used to calculate the hourly burden estimates in table 56 based on the following calculations:

START OF CARE		
Estimated time spent per each 2027 OASIS SOC Assessment/Patient = 57.3 clinician minutes		
204 data elements x (range of 0.15 to 0.3) minutes per data element = 57.3 minutes of clinical time spent to complete data entry for the OASIS SOC assessment.		
• 23 data elements counted as 0.15 minutes/data element (3.45 minutes).	• 9 data elements counted as 0.25 minutes/ data element (2.25 minutes).	• 172 data elements counted as 0.30 minutes/ data element (51.6 minutes).
Clinician Estimated hourly burden for all HHAs (11,904) for 2027 OASIS SOC assessments = 8,228,553 hours		
57.3 clinician minutes per SOC assessment x 8,616,286 assessments = 493,713,188 minutes/60 minutes per hour = 8,228,553 hours for all HHAs		
Clinician Estimated hourly burden for all HHAs (11,904) for 2027 OASIS SOC assessments = 8,228,553 hours		
Estimated time spent per each 2026 OASIS SOC Assessment/Patient = 56.4 clinician minutes.		
200 data elements x (range of 0.15 to 0.3) minutes per data element = 56.4 minutes of clinical time spent to complete data entry for the OASIS-E1 SOC assessment.		
• 21 data elements counted as 0.15 minutes/data element (3.15 minutes).	• 9 data elements counted as 0.25 minutes/data element (2.25 minutes).	• 170 data elements counted as 0.30 minutes/data element (51 minutes).
Clinician Estimated hourly burden for all HHAs (11,904) for 2026 OASIS SOC assessments = 8,099,309 hours		
56.4 clinician minutes per SOC assessment x 8,616,286 assessments = 485,958,530 minutes/60 minutes per hour = 8,099,309 hours for all HHAs.		

RESUMPTION OF CARE

Estimated time spent per each **2027** OASIS ROC Assessment/Patient = 48 minutes

172 data elements x (range of 0.15 to 0.3) minutes per data element = 48 minutes of clinical time spent to complete data entry for the OASIS ROC assessment

- 21 data elements counted as 0.15 minute/data element (3.15 minutes)

- 9 data elements counted as 0.25 minute/data element (2.25 minutes)

- 142 data elements counted as 0.30 minute/data element (42.6 minutes)

Clinician Estimated Hourly Burden for all HHAs for **2027** OASIS ROC assessments = 947,694 hours

48 clinician minutes per ROC assessment x 1,184,618 ROC assessments = 56,861,664 minutes/60 minutes = 947,694 hours for all HHAs

Estimated time spent per each **2026** OASIS-E1 ROC Assessment/Patient = 47.1 minutes

168 data elements x (range of 0.15 to 0.3) minutes per data element = 47.1 minutes of clinical time spent to complete data entry for the OASIS-E1 ROC assessment

- 19 data elements counted as 0.15 minute/data element (2.85 minutes)

- 9 data elements counted as 0.25 minute/data element (2.25 minutes)

- 140 data elements counted as 0.30 minute/data element (42 minutes)

Clinician Estimated Hourly Burden for all HHAs for **2026** OASIS-E1 ROC assessments = 823,310 hours

47.1 clinician minutes per ROC assessment x 1,184,618 ROC assessments = 55,795,508 minutes/60 minutes = 929,925 hours for all HHAs

TRANSFER OF CARE

Estimated time spent per each **2027** OASIS TOC Assessment/Patient = 6.9 minutes

23 data elements x 0.3 minutes per data element = 6.9 minutes of clinical time spent to complete data entry for the OASIS TOC assessment

- 23 data elements counted as 0.3 minutes/ data element (6.9 minutes)

Clinician Estimated Hourly Burden for all HHAs for **2027** OASIS TOC assessments = 271,927 hours

6.9 clinician minutes per TOC assessment x 2,364,588 TOC assessments = 16,315,657 minutes/60 minutes = 271,927 hours for all HHAs

Estimated time spent per each **2026** OASIS TOC Assessment/Patient = 6.6 minutes

22 data elements x 0.3 minutes per data element = 6.6

- 22 data elements counted as 0.3 minutes/data element (6.6 minutes)

Clinician Estimated Hourly Burden for all HHAs for **2026** OASIS TOC assessments = 260,105 hours

6.6 clinician minutes per TOC assessment x 2,364,588 TOC assessments = 15,606,281 minutes/60 minutes=260,105 hours for all HHAs

DEATH AT HOME		
Estimated time spent per each 2027 OASIS-E1 DAH Assessment/Patient = 3 minutes		
10 data elements x 0.3 minutes per data element = 3 minutes of clinical time spent to complete data entry for the OASIS DAH assessment		
• 10 data elements counted as 0.3 minutes/data element (3 minutes)		
Clinician Estimated Hourly Burden for all HHAs for 2027 OASIS DAH assessments = 3,146 hours		
3 clinician minutes per DAH assessment x 62,917 DAH assessments = 188,751 minutes/60 minutes=3,146 hours for all HHAs.		
Estimated time spent per each 2026 OASIS-E1 DAH Assessment/Patient = 2.7 minutes		
• 9 data elements counted as 0.3 minutes/data element (2.7 minutes)		
Clinician Estimated Hourly Burden for all HHAs for 2026 OASIS DAH assessments = 2,831 hours		
2.7 clinician minutes per DAH assessment x 62,917 DAH assessments = 169,876 minutes/60 minutes=2,831 hours for all HHAs		

DISCHARGE		
Estimated time spent per each 2027 OASIS DC Assessment/Patient = 40.2 minutes		
146 data elements x (range of 0.15 to 0.3) minutes per data element = 40.2 minutes of clinical time spent to complete data entry for the OASIS-E1 DC assessment		
• 21 data elements counted as 0.15 minutes/data element (3.15 minutes)	• 9 data elements counted as 0.25 minutes/data element (2.25 minutes)	• 116 data elements counted as 0.30 minutes/data element (34.8 minutes)
Clinician Estimated Hourly Burden for all HHAs for 2027 OASIS DC assessments = 4,694,090 hours		
40.2 clinician minutes per DC assessment x 7,006,104 DC assessments = 281,645,381 minutes/60 minutes =4,694,090 hours for all HHAs		
Estimated time spent per each 2026 OASIS DC Assessment/Patient = 39.9 minutes		
145 data elements x (range of 0.15 to 0.3) minutes per data element = 39.9 minutes of clinical time spent to complete data entry for the OASIS DC assessment		
• 21 data elements counted as 0.15 minute/data element (3.15 minutes)	• 9 data elements counted as 0.25 minute/data element (2.25 minutes)	• 115 data elements counted as 0.30 minute/data element (34.5 minutes)
Clinician Estimated Hourly Burden for all HHAs for 2026 OASIS DC assessments = 4,659,059 hours		
39.9 clinician minutes per DC assessment x 7,006,104 DC assessments = 279,543,550 minutes/60 minutes = 4,659,059 hours for all HHAs		

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Table 56 summarizes the estimated clinician hourly burden for the OASIS that would be implemented in 2026 with this proposed rule's changes of a decrease in four data elements at start of care and resumption of care and a

decrease in a data element at transfer of care, death at home, and discharge compared to the anticipated 2027 OASIS burden if these reductions were not implemented. This is calculated by multiplying the total number of assessments by the decrease in

assessment time required. We calculate the 2027 and 2026 burden estimates in minutes and then calculate hourly burden estimates shown in Table 56. We estimated a net decrease of 194,181 hours of clinician burden across all

HHAs or 16,31 hours (194,181/11,904) for each of the 11,904 active HHAs.

TABLE 56. SUMMARY OF ESTIMATED CLINICIAN HOURLY BURDEN FOR CY 2027 AND CY 2026 OASIS

OASIS Assessment Type	Clinician Estimated SOC/ROC Hourly Burden – OASIS 2027	Clinician Estimated SOC/ROC Hourly Burden – OASIS 2026	Total Decrease in Hours
Start of Care	8,228,553	8,099,309	-129,244
Resumption of Care	947,694	929,925	-17,769
Transfer of Care	271,927	260,105	-11,822
Death at Home	3,146	2,831	-315
Discharge	4,694,090	4,659,059	-35,031
Totals	14,145,410	13,951,229	-194,181

Table 56 summarizes the estimated clinician costs for the 2027 OASIS and the 2026 OASIS with the net reduction of four data elements at start of care and resumption of care and one data element removed from transfer of care, death at home, and discharge using CY 2024 BLS wage inputs. Total clinician cost for 2027 and 2026 is estimated by multiplying total hourly burden for each year as reported in table 43 by the weighted clinician average hourly wage of \$91.72. Then we calculate the difference in clinician-estimated costs between 2027 and 2026. This calculates the estimated decrease in costs

associated with adding the four data elements at the start of care and resumption of care and removing a data element at transfer of care, death at home, and discharge. For the COVID–19 items collected at transfer of care, death at home, and discharge, we estimate a decrease in clinician cost of \$4,326,249 or \$363 (\$4,326,249/11,904) for each of the 11,904 active HHAs. For the four SDOH data elements removed at the start of care or resumption of care, we estimate a decrease in clinician cost of \$13,484,033 or \$1,132 (\$13,484,033/ 11,904) for each of the 11,904 active HHAs. For all proposals, we estimate a

decrease in clinician costs of \$17,786,980 between 2027 and 2026 related to the implementation of the proposals outlined in this proposed rule across all HHAs or a \$1,494 decrease (– \$17,786,980/11,904) for each of the 11,904 active HHAs. This decrease in burden will begin with the April 1, 2026, OASIS assessments.

The burden estimates detailed in this section will be submitted for OMB review and approval as part of revision of the information collection request currently approved under OMB control number 0938–1279.⁹⁷

TABLE 57. SUMMARY OF ESTIMATED CLINICIAN COSTS FOR CYs 2027 AND 2026

OASIS Assessment Type	Clinician Estimated Cost – OASIS 2027	Clinician Estimated Cost – OASIS-E1 2026	Total Cost Increase
Start of Care	\$754,722,881	\$742,868,621	-\$11,854,260
Resumption of Care	\$86,922,494	\$85,292,721	-\$1,629,773
Transfer of Care	\$24,941,144	\$23,856,831	-\$1,084,313
Death at Home	\$288,551	\$259,659	-\$28,892
Discharge	\$430,541,935	\$427,328,891	-\$3,213,044
Totals	\$1,297,417,005	\$1,279,606,723	-\$17,810,282

2. ICRs for the Expanded HHVBP Model

a. ICRs for the Proposed Changes to the Measure Removal Factors

The proposed changes to the measure removal factors, proposed changes to the HHVBP applicable measure set, and the RFI for the expanded HHVBP Model included in section IV. of this proposed rule do not result in an increase in costs to HHAs. Section 1115A(d)(3) of the Act

exempts Innovation Center model tests and expansions, which include the expanded HHVBP Model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA do not apply to the testing and evaluation of Innovation Center models or to the expansion of such models.

b. ICRs for the Proposed Modification of the HHCAHPS Survey

Beginning with the CY 2027 Public Reporting Period/CY 2028 Payment Determination as described in section III.H. of this proposed rule, we are proposing to modify the HHCAHPS Survey measure beginning in April 2026. Specifically, the updated measures include updates to the Care of Patients and Communication between

⁹⁷ The currently approved OASIS information collection request expires 12/31/2027. [https://](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202406-0938-007)

www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202406-0938-007.

Providers and Patients measures, and removal of Specific Care Issues measure and replacing this measure with three single-item measures related to reviewing home safety, reviewing medications and discussing side effects of medications. As part of these changes, the HHCAHPS Survey is being reduced by 8 survey items. Under OMB control number 0938–1066,⁹⁸ we estimate the time to complete the current HHCAHPS Survey to be approximately 12 minutes per respondent and approximately 1,043,447 respondents would complete and submit the HHCAHPS Survey as part of the Home Health Quality Reporting Program annually. We estimate the combination of survey removals and additions would result in a decrease of 3 minutes (.05 hour) per respondent to complete the updated version of the HHCAHPS Survey. Therefore, we estimate the updated time to complete the shorter HHCAHPS Survey would be 9 minutes per respondent (0.15 hour) at \$32.66 per hour.⁹⁹ Our estimate is based on the written length of the survey and CMS's experience with the revised survey during the mode experiment (CMS 10784, OMB control number 0938–1404). In aggregate, we estimate a burden of 153,884 hours (1,025,894 patients (updated estimated of number of patients) × 0.15 hr.) at a cost of \$5,025,851 (153,884 hr. × \$32.66/hr.) or \$4.90 per survey (\$5,025,851/1,025,894 patients). The burden estimates detailed in this section will be submitted for OMB review and approval as part of revision of the information collection

request currently approved under OMB control number 0938–1066.

3. ICRs for Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements

As discussed in section V. of this proposed rule, we are proposing technical revisions to the HH CoPs to further clarify that the existing requirement for reporting OASIS information applies to all HHA patients receiving skilled services. This technical change seeks to provide clarity by creating alignment between the terminology used in the CoPs and requirements for data collection and submission to OASIS for purposes of the HH QRP. It does not propose any revisions to the specific requirements for submitting data to OASIS and does not have any bearing on the change to expand the data collected that was finalized in the CY 2023 HH PPS final rule (87 FR 66862). Therefore, this technical change would not result in an increase in costs for HHAs. For a review of the burden and operational costs associated with the transition to the OASIS all-payer submission requirements we refer readers to the CY 2023 HH PPS final rule "Collection of Information" section (88 FR 66877) and to the CY 2024 HH PPS final rule for the latest burden estimates (88 FR 77676).

4. Medicare and Medicaid Provider Enrollment

As discussed in section VI.A. of this proposed rule, we are proposing several changes to our Medicare provider enrollment regulations, with one minor

revision to a Medicaid provider enrollment provision in 42 CFR part 455, subpart E. Except as otherwise explained in this section VIII. of this proposed rule, we do not believe that any of our proposed provider enrollment provisions implicate an ICR burden.

a. Submission of Additional Documentation

We are proposing to add new paragraph (C) to § 424.510(d)(2)(iii) such that CMS could require a provider or supplier to submit any documentation (that is, documentation beyond that currently required under § 424.510(d)(1)) to verify and confirm the information furnished on the enrollment application; this includes, but is not limited to, documentation regarding the provider's or supplier's ownership or management. We cannot predict the number or types of providers and suppliers that would be requested to provide such documentation or the specific documentation involved, for it would vary widely by provider and supplier. Nonetheless, we believe a general estimate, solely for purposes of this ICR section, is possible.

In terms of cost, it has been our experience that Form CMS–855 applications are completed by the provider's or supplier's office staff. Accordingly, we would use the following wage category and hourly rate from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates for all salary estimates (<https://data.bls.gov/oes/#/industry/000000>).

TABLE 58: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES – PROVIDER ENROLLMENT

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Office and Administrative Support Workers, All Other	43-9199	22.14	22.14	44.28

We anticipate that: (1) most of the requested documentation would be that which helps validate the provider's or supplier's ownership and management; (2) 5,000 providers and suppliers per year would have to secure and submit it; and (3) it would take the provider or

supplier 15 minutes (0.25 hr) to do so. This results in an annual burden of 1,250 hours and \$55,350 (\$44.28 × 5,000 × 0.25).

b. DMEPOS Liability Insurance

To enroll and maintain enrollment in the Medicare program, DMEPOS suppliers under § 424.57(c)(10) must have a comprehensive liability insurance policy of at least \$300,000

⁹⁸ The currently approved HHCAHPS information collection request expires July 31, 2026.

⁹⁹ To derive the average costs for individuals, we used data from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates for our salary estimate

(www.bls.gov/oes/current/oes_nat.htm). We believe that the burden will be addressed under All Occupations (occupation code 00–0000) at \$32.66/hr. since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of

employment, and educational attainment, etc. Unlike our private sector adjustment to the respondent hourly wage (see below), we are not adjusting this figure for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

that covers the supplier's place of business, customers, and employees. We are proposing to revise § 424.57(c)(10) such that an "authorized official" of the DMEPOS supplier (as that term is defined in § 424.502) must sign the liability insurance policy. We do not have data indicating the number of DMEPOS suppliers whose liability insurance policies are signed by: (1) an authorized official; or (2) someone of equivalent status within the organization who nonetheless may not be listed as an authorized official on the supplier's application. Therefore, we are unable to project any ICR burden associated with our proposed change. However, we solicit comment from the DMEPOS supplier community on the possible burden.

c. Miscellaneous

We are also proposing in § 424.516 to reduce the timeframe in which a provider or supplier must report an adverse legal action to CMS from 90 days to 30 days. We wish to clarify for stakeholders that we do not believe this would result in a change in provider burden. This is because regardless of the reporting timeframe involved, the change must be reported; that is, only

the timeframe for disclosure is changing, not the burden.

5. DMEPOS Supplier Accreditation Organizations (AOs)

Section 424.57 requires that DMEPOS suppliers be accredited by a CMS-approved AO to enroll in and bill the Medicare program. The main purpose of accreditation is to confirm—typically via a survey of the DMEPOS supplier's location—that the supplier meets detailed quality standards involving, for example, its administration, financial management, customer service, and DMEPOS product safety. Section 424.58, which was promulgated in 2006, outlines some of the components and requirements of the DMEPOS accreditation program, which CMS oversees but the AOs largely operate. These components include but are not limited to: (1) the process via which an organization can apply to become an AO; and (2) AO submission of accreditation data to CMS. However, two core concerns have arisen regarding aspects of the DMEPOS accreditation program. First, Medicare fraud, waste, and abuse among DMEPOS suppliers has continued notwithstanding the accreditation requirement. Second, we believe that the current provisions in

§ 424.58 must be strengthened to help ensure that AOs are adequately executing their DMEPOS accreditation activities. In our view, and as explained in section VI.B. of this proposed rule, we believe additional requirements are needed and are proposing a number of them. This section VIII. of this proposed rule outlines the estimated ICR burden associated with several of these data categories. Other costs would be addressed in the regulatory impact analysis (RIA) of this proposed rule. We note that only those categories that involve a new burden—that is, above and beyond the current provisions of § 424.58—would be addressed.

a. Submission of Data During AO Initial Application and Reapproval Application

Current § 424.58(b) (which would become new paragraphs (c) and (d)) outlines information that organizations must submit when applying or reapplying to become a DMEPOS AO. We are proposing additional data that must be provided in these situations. These data elements are outlined in Table 59, which also lists our estimated hour burden of compiling, preparing, drafting, and submitting this information.

TABLE 59: NEW DATA SUBMISSION ELEMENTS IN PROPOSED § 424.58(c) AND (d)

Regulatory Citation in Revised § 424.58(c)	Data Element	Estimated Hour Burden Per Submission
(c)(1)(iii)	Description of survey and other accreditation processes	4
(c)(1)(iii)(G)	How AO determines whether to perform survey (including sampling methodology)	2
(c)(1)(vii)(D)	Policies/procedures for avoiding conflicts of interest (including consulting firewall policies)	2
(c)(1)(vii)(E)	Policies/procedures for ensuring adequate number of surveyors	2
(c)(1)(viii)	Process for identifying/addressing deficiencies within its accreditation program	3
(c)(1)(ix)	How AO uses data to ensure compliance with Medicare program requirements	3
(c)(1)(x)(A) and (B)	Outline of steps AO would take in reviewing complaints and determining compliance	3
(c)(xvi)	Information demonstrating AO's DMEPOS knowledge/expertise/experience	2
(c)(xvii)	Information on AO's ability to conduct timely application reviews	2
(c)(xviii)	Description of decision-making process (including approving/denying/terminating a DMEPOS supplier's accreditation and the reasons for denial or termination)	4
(c)(xix)	Policies/procedures for determining whether/when survey is performed and ensuring unannounced surveys	2
(c)(xx)	Policies/procedures for when CAP applied	4
(c)(xxi)	Explanation of what AO deems and defines as deficiency and levels thereof	2
(c)(xxii)	Processes for detecting/reporting fraud, waste, and abuse	3
(c)(xxiii)	Signed statement/agreement	6
(c)(2)	Submission of additional application information per CMS request	8
Total Hour Burden Per Application Submission		52

As we believe that clinicians (such as nurses) and AO managers would be

most likely to prepare and submit the application, we propose to use the

following May 2024 BLS median wage categories:

TABLE 60: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Registered Nurses	29-1141	45.00	45.00	90.00
Medical and Health Services Managers	11-9111	56.71	56.71	113.42
Office and Administrative Support Workers, All Other	43-9199	22.14	22.14	44.28
General and Operations Managers	11-1201	49.50	49.50	99.00

The aforementioned statement in § 424.58(c)(1)(xxiii) must be signed by the AO's chief executive officer (CEO) or someone with equivalent authority within the AO. To account for this task, we would also use May 2024 BLS median wage category of "Chief Executives" (Occupation Code 11-1011). The wage amount is \$99.24; with fringe benefits and overhead, it is \$198.48.

There are currently 8 CMS-approved DMEPOS AOs. For purposes of this ICR estimate only, we would assume that all 8 would apply for reapproval sometime within the next 3-year timeframe (which is the standard OMB approval period) and that 2 organizations would initially apply for AO approval. This would result in a total hour burden for this period of 520 hours (52 hours $\times$ 10 organizations). Of these 520 hours, 10 hours (or 1 hour for each of the 10 AOs) would involve the CEO's review and signature of the statement, resulting in a cost of \$1,985 (10 $\times$ \$198.48). As for the remaining 510 hours, we believe that nurses and the aforementioned managers would be equally involved in preparing the application. We would hence use a midpoint wage estimate of \$101.71 ((\\$90.00 + \$113.42)/2). This results in a total 3-year cost of \$53,857 ((\\$101.71 $\times$ 510 hours) + \$1,985), with an annual burden of 173 hours and \$17,952.

Except as otherwise noted, we would use the \$101.71 wage figure for the remainder of our DMEPOS accreditation ICR estimates.

b. Monthly Submission of Data

Existing § 424.58(c)(1) (proposed new paragraph (e)(1)(i)) requires AOs to submit certain data to CMS on a monthly basis (for example, notice of accreditation decisions). We are proposing in new paragraph (e)(1) that each AO must also—as part of its monthly submission to CMS—furnish notice of: (1) the instances where the AO had the discretion to perform a survey but decided not to (including the reason for the AO's decision); and (2) all

currently resolved deficiencies among its DMEPOS suppliers.

Although we cannot determine how many DMEPOS AOs there would be over the next 3 years, we would—for purposes of this ICR only—use the current number of 8 AOs.

We estimate it would take an AO a total of 6 hours each month to compile and submit the data in (1) and (2). (That is, about 3 hours for each task.) This would result in an ICR burden over 3 years of 1,728 hours (6 hours $\times$ 8 AOs $\times$ 12 months $\times$ 3 years) at a cost of \$175,755 (1,728 hours $\times$ \$101.71), with the annual burden being 576 hours and \$58,585.

c. CMS Ad-Hoc Data Requests

Proposed new paragraph (e)(1)(ii) would state that CMS may at any time request the AO to submit any of the information described in paragraph (e)(1)(i); this data must be furnished to CMS within 3 business days of the request. We cannot predict the number of instances where CMS would request this data or the specific information that would be solicited. However, solely for purposes of this ICR, we estimate that we would request paragraph (e)(1)(i) data from each AO 3 times per year and that it would take the AO 3 hours to accumulate data for each request. This would result in a 3-year burden of 216 hours (3 hours $\times$ 3 requests $\times$ 8 AOs $\times$ 3 years) and \$21,969 (216 $\times$ \$101.71). The annual burden would be 72 hours and \$7,323.

d. Notice to CMS of Changes to the AO's Accreditation Standards, Requirements, or Survey Process

Among the monthly data the AO must submit under current paragraph (c)(1)(v) is notice of any changes to the AO's accreditation standards, requirements, or survey process. We are proposing to remove this provision from the monthly reporting requirement and instead in new paragraph (e)(2) require the AO to: (1) report such changes to us 60 days before the planned effective date; and (2) submit detailed information about the changes, the rationale for them, and

an accompanying crosswalk. We do not expect the 60-day requirement to impose an additional burden since the changes would still be reported to us, but we believe the additional information in (2) that must be furnished would.

Per our experience, each AO undertakes and reports these program revisions to us about twice per year. We estimate that the additional details that must be submitted would take 2 hours for the AO to compile. The resulting 3-year burden would thus be 96 hours (2 per year $\times$ 2 hours $\times$ 8 AOs $\times$ 3 years) and \$9,764 (96 $\times$ \$101.71), with the annual burden being 32 hours and \$3,255.

e. Submission of Complaint Data

AOs under existing § 424.58(c)(1)(iii) must report to CMS each month all complaints related to DMEPOS suppliers. We are proposing to remove this requirement from § 424.58(c)(1)(iii) and establish a new paragraph (e)(3) devoted exclusively to complaints. There are two new proposed ICR-related provisions therein. Specifically—

- Upon receipt of a complaint, the AO must notify CMS in writing of the complaint within 5 calendar days of receiving it.
- Notify CMS in writing of the result of its review of the complaint, the result of the survey, or of any action the AO took against the supplier.

The more frequent reporting of complaints to CMS—as well as notice of the results of the AO's investigation—would constitute an additional ICR burden. Given the number of complaints currently reported to us on a monthly basis, we estimate that each AO would annually report 50 complaints to us and, in turn, submit 50 investigation reports to us. We project that the former would take 1 hour to complete and submit and the latter 3 hours, for an average of 2 hours. This results in a 3-year burden of 4,800 hours ((50 complaint reports + 50 investigation reports) $\times$ 2 hours $\times$ 8 AOs $\times$ 3 years) at a cost of \$488,208 (4,800 $\times$ \$101.71), with the annual burden being 1,600 hours and \$162,736.

f. Corrective Action Plans (CAPs)

New paragraph (e)(4) would require AOs to notify CMS in writing of any decision to apply a CAP to a specific supplier within 10 calendar days of the decision. The notice must include: (1) the reason for the decision; (2) a detailed explanation and justification as to why the AO applied a CAP instead of revoking the supplier's accreditation; and (3) the details of the supplier's CAP. We believe that each AO would submit approximately 75 such notices to CMS per year and that each notice would take 2 hours to complete. The 3-year burden would therefore be 3,600 hours (75 submissions $\times$ 2 hours $\times$ 8 AOs $\times$ 3 years) and \$366,156 (3,600 $\times$ \$101.71). The annual burden would be 1,200 hours and \$122,052.

g. Denials and Terminations of DMEPOS Supplier's Accreditation

Under proposed § 424.58(e)(5)(i), the AO must notify CMS in writing of any decision to deny accreditation to (or terminate the accreditation of) a DMEPOS supplier within 5 calendar days of the decision; the notification must include the reason for the denial or termination. While AOs are currently required under § 424.58(c)(1)(iv) to report DMEPOS supplier terminations to CMS on a monthly basis, new paragraph (e)(5) would increase the frequency with which this information must be provided. We project that each AO would submit approximately 100 such reports to CMS each year. Each report would take 2 hours to prepare and submit. This would result in a 3-year burden of 4,800 hours (100 reports $\times$ 8 AOs $\times$ 3 years $\times$ 2 hours) and \$488,208 (4,800 $\times$ \$101.71) and an annual burden of 1,600 hours and \$162,736.

Proposed § 424.58(e)(5)(ii)(A)(5) would require an AO to deny or terminate a DMEPOS supplier's accreditation if directed by CMS. The AO under § 424.58(e)(5)(ii)(B)(2) would also have to notify CMS in writing that it has taken the directed action. We estimate that each year an AO would submit roughly 20 notices to CMS and that it would take 0.5 hours for the AO to do so each time. The total 3-year burden would thus be 240 hours (20

reports $\times$ 0.5 $\times$ 8 AOs $\times$ 3 years) and \$24,410 (240 hours $\times$ \$101.71). The annual burden would be 80 hours and \$8,137.

h. Voluntary Terminations

New § 424.58(g) would outline procedures via which an AO can voluntarily withdraw from the DMEPOS accreditation program. Part of this process involves: (1) notifying CMS in writing of its decision; and (2) provide written notice to each of its accredited DMEPOS suppliers. For purposes of this ICR only, we estimate that 1 DMEPOS AO over a 3-year period would voluntarily terminate its accreditation and that the tasks in (1) and (2) would take the AO 6 hours combined to complete (mostly involving the second task, which we believe would be done via a listserv message to all suppliers) at a cost of \$610 (1 $\times$ 6 hours $\times$ \$101.71). The annual burden would be 2 hours and \$203.

i. Involuntary Terminations

New § 424.58(h)(4) would require a terminated AO to provide written notice of the termination to each of its accredited DMEPOS suppliers. As with voluntary terminations, we estimate that 1 DMEPOS AO over a 3-year period would have its CMS approval terminated. We estimate it would take the AO 6 hours to notify its DMEPOS suppliers of the termination via a listserv message. This would result in a 3-year burden of 6 hours at a cost of \$610. The annual burden would be 2 hours and \$203.

j. Acknowledgement of Suspension and Lifting Thereof

New § 424.58(i) states that if CMS notifies the AO that its accreditation program has been suspended, the AO must send CMS a written acknowledgment of CMS' notice. Likewise, the AO must notify CMS in writing of its acknowledgment of a CMS notification that the suspension has been lifted. We project that 1 AO over a 3-year period would be suspended and that each of the two acknowledgments would take 1 hour to complete and submit. The 3-year burden would hence be 2 hours (1 hour $\times$ 2 acknowledgments) at a cost of \$203. The

annual burden would be 0.667 hours and \$68.

k. Conflicts of Interest and Consulting

New § 424.58(m) and (n) would establish requirements regarding AO consulting services and conflicts of interest, respectively. There are two principal ICR aspects of these requirements:

- The AO's submission of a report upon CMS request regarding any consulting activities it has engaged or is engaging in (paragraph (m)(4)).

- Preparation and submission to CMS (upon the latter's request) of the AO's written consulting firewall policies (paragraph (m)(5)).

(These documents must also be submitted with an AO's request for initial approval or reapproval of its DMEPOS accreditation program, though the burden associated with this is included in the ICR calculations for AO initial and reapproval applications.)

We project that the report in paragraph (m)(4) would take an AO 2 hours to complete and submit and that CMS would request it twice per year. This would result in a 3-year burden of 96 hours (2 reports per year $\times$ 2 hours $\times$ 8 AOs $\times$ 3 years) and \$9,764 (96 $\times$ \$101.71), or 32 hours and \$3,255 annually. Regarding the firewall policies and procedures, we estimate that it would take the AO 2 hours to prepare and submit these policies and that CMS would request them once a year. The 3-year burden of this activity would be 48 hours (2 hours $\times$ 1 request per year $\times$ 8 AOs $\times$ 3 years) and \$4,882, or 16 hours and \$1,627 per year. The combined annual ICR burden of the requirements of paragraph (m) are 48 hours (32 + 16) and \$3,973 (\$3,255 + \$1,627).

l. AO Changes of Ownership

We are proposing in new § 424.58(o) procedures for which a DMEPOS AO can undergo a change of ownership. Said procedures would be those outlined in § 488.5(f). The latter section contains several actions that we believe would have ICR implications for an AO changing its ownership. Table 61 outlines these actions and the estimated time burden of completing each of them:

TABLE 61: NEW DATA SUBMISSION ELEMENTS IN PROPOSED § 424.58(o)

Regulatory Citation in § 488.5(f)	Action	Estimated Hour Burden Per Action
(f)(1)	DMEPOS AO contemplating or negotiating a change of ownership must notify CMS in writing.	2
(f)(2)(iii)	Prospective AO buyer must submit detailed data in its request for approval of transfer of AO's current approval to the buyer (that is, identifying information, financial statements, transition plan, policies to avoid conflicts of interest)	135
(f)(3) and (4)(ii)	Prospective AO buyer's submission of written acknowledgments to CMS.	2
(f)(4)(i) *	All parties to the transaction must notify all affected DMEPOS suppliers of any CMS approval of the transfer.	12
(f)(5)	Prospective AO buyer notifies CMS in writing that the change of ownership has occurred.	1
TOTAL		152

* Takes into account the aforementioned 6-hour supplier notification burden for voluntary and involuntary terminations.

Regarding the 135-hour burden for § 488.5(f)(2)(iii), we note that we published a final rule in the April 29, 2022, **Federal Register** on titled “Medicare Program; Accrediting Organizations—Changes of Ownership” (87 FR 25413). This final rule added new requirements processes for AO changes of ownership. The estimated burden therein for the activity in § 488.5(f)(2)(iii) was 135 hours, and the material to be submitted would be prepared by individuals in the BLS wage categories of Registered Nurse, Medical or Health Services Manager, and Accountant or Auditor (Occupation Code 13–2011). Therefore, we would use this hour burden for paragraph (f)(2)(iii) (as applied to DMEPOS AO ownership changes) and a combined average wage for these three BLS categories. We previously mentioned the wages for the first two categories, \$90.00 and \$113.42. For accountants and auditors, the median wage with fringe benefits and overhead is \$78.54. The average of these three figures is \$93.99.

We would assume for purposes of this ICR that 1 DMEPOS AO over a 3-year period would undergo a change of

ownership. Using our total hour burden from table 62, this would result in a 3-year burden of 152 hours and \$14,286. The annual burden would be 51 hours and \$4,762.

m. DMEPOS Supplier Change in Majority Ownership

We are proposing in new § 424.551 that a DMEPOS supplier that undergoes a change in majority ownership (CIMO) (as that term is defined in § 424.551) that does not qualify for an exception under that section must enroll in Medicare as an initial DMEPOS supplier, obtain a new accreditation, and receive an accreditation survey. This would require completion of an initial Form CMS–855S Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers,¹⁰⁰ OMB No.: 0938–1056).

We are projecting in section IX. of this proposed rule that an average of 3,768 DMEPOS suppliers each year have a CIMO. We currently require any DMEPOS supplier undergoing a change of ownership involving a new tax identification number to enroll in Medicare as a new supplier. Since these

suppliers already have to complete a new enrollment application, there would be no change in their Form CMS–855S information collection burden. Although we do not have concrete estimates as to what portion of the above 3,768 suppliers fall into this category, we believe it is roughly 400–500. We will therefore base our Form CMS–855S burden projections on an estimated 3,300 affected suppliers.

Per previous projections, completion of an initial Form CMS–855S application takes approximately 4 hours, resulting in an annual time burden of 13,200 hours (3,300 hours × 4). In terms of costs, office and administrative support workers (BLS median wage of \$44.28) complete the application for a 3.5-hour burden, and a general and operations manager (\$99.00 wage) spends 0.5 hours reviewing and signing the form. This results in an annual cost burden of \$674,784 ((3.5 hours × 3,300 × \$44.28) + (0.5 hours × 3,300 × \$99.00)).

n. Totals

Table 62 outlines the annual ICR burdens associated with our proposed DMEPOS accreditation provisions:

¹⁰⁰ The currently approved CMS–855S information collection request expires 12/31/2025.

TABLE 62: ANNUAL ICR BURDEN ESTIMATES FOR DMEPOS AO REQUIREMENTS

	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$) (includes 100% fringe benefits)	Total Cost (\$)
Submission of Additional Initial Application and Reapproval Application Data	0938-New	4	4	Varies	173	101.71	17,596
Submission of Additional Monthly Data	0938-New	8	96	6	576	101.71	58,585
Ad-Hoc CMS Data Requests	0938-New	8	24	3	72	101.71	7,323
Notice of Changes in AO's Standards/Requirements	0938-New	8	16	2	32	101.71	3,255
Complaint Reports	0938-New	8	800	2 (average)	1,600	101.71	162,736
CAPs	0938-New	8	600	2	1,200	101.71	122,052
Denials/Terminations of Supplier's Accreditation Reports to CMS	0938-New	8	800	2	1,600	101.71	162,736
Notice to CMS that AO Denied/Terminated Supplier's Accreditation Per CMS Direction	0938-New	8	160	0.5	80	101.71	8,137
Voluntary Terminations – Notice to CMS and Suppliers	0938-New	0.333	0.333	6	2	101.71	203
Involuntary Termination – Notice to Suppliers	0938-New	0.333	0.333	6	2	101.71	203
Acknowledgment of Suspension and Lifting Thereof	0938-New	0.333	0.333	1	0.333	101.71	34
Consulting Data	0938-New	8	24	Varies	48	101.71	4,882
AO Changes of Ownership	0938-New	0.333	0.333	Varies	51	93.99	4,793
Completion of Initial Form CMS-855S	0938-1056	3,300	3,300	4	13,200	Varies	674,784
TOTALS (Rounded to Nearest Whole Dollar)	N/A	3,369	5,825	Varies	18,636	Varies	1,227,319

The costs of our DMEPOS accreditation proposals to DMEPOS suppliers—as well as additional costs to DMEPOS AOs—are addressed in section IX.C.6. of this proposed rule.

We solicit comment from stakeholders regarding any potential DMEPOS accreditation ICR burdens that may not have been addressed in this section VIII.B.5. of this proposed rule. The burden estimates detailed in this section will be submitted for OMB review and approval as part of new information collection request, that is, a request for a new OMB control number.

6. ICRs for Proposed Exemption Process for Prior Authorization of Certain DMEPOS Items (§ 414.234(c)(1) and (c)(1)(ii))

We propose to add technical language to § 414.234(c)(1) that provides for the exemption process in § 414.234 (c)(1)(ii). We also propose to exempt a supplier from the mandatory prior authorization process (OMB Control No. 0938–1293) in newly proposed § 414.234(c)(1)(ii)(A) upon demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS withdraws the exemption. In proposed § 414.234 (c)(1)(ii)(B), we would provide 60-day notice of an exemption from mandatory prior authorization requirements. Similarly, we propose to provide 60-day notice if an exemption is withdrawn. We would exempt suppliers that achieve a prior authorization provisional affirmation threshold of at

least 90 percent during a periodic assessment. If the rate of prior authorizations with non-affirmations submitted becomes higher than 10 percent during an annual assessment, we would consider withdrawing exemption for the specific noncompliant supplier, until the following periodic assessment.

We estimate there would be savings for compliant suppliers who meet the 90 percent affirmation threshold. We based our savings estimates on presumptions, which we would discuss herein, and internal data obtained from the DME MACs. Compliant suppliers would not have to submit prior authorization requests (PARs). The burden associated with submitting prior authorization requests is the time and effort necessary for the submitter to locate and obtain the supporting documentation for the prior authorization request and to forward the materials to the MAC for review. CMS expects that this information would generally be maintained by suppliers as a normal course of business and that this information would be readily available. The documentation submitted must support medical necessity for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Medicare benefit eligibility, and meet all other applicable Medicare statutory and regulatory requirements.

a. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics'

(May 2024 Occupational Employment Statistics report) to find the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. Based on the Bureau of Labor Statistics report (Healthcare Support Occupations), we estimate an average hourly rate of \$19.06 with a loaded rate of \$38.12.

The process of submitting, and unit cost of reviewing expedited prior authorization requests is the same for standard review. Items on the Required Prior Authorization List are rarely used in emergent situations, consequently, we expect the request for expedited reviews to remain low.

In addition to mail, suppliers can submit documentation through fax, electronic portals, and esMD, so supplier burden should not be affected by the method of submission. CMS estimates that the average time for office clerical activities associated with this task to be 30 minutes. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the BLS.

We based the estimated number of responses for Year 1 on the number of prior authorization requests for the DMEPOS items currently on the Required Prior Authorization List for Calendar Year 2024. We estimate a 3 percent increase in the number of PARs received in CYs 2024, 2025, and 2026. In Year One (CY 2026) we anticipate that there would be 232,836 initial requests and 57,017 resubmissions.

We estimate around 30,000 initial prior authorization requests for DMEPOS items that could potentially be added to the Required Prior Authorization List in the future. Of these, we estimate only 80 percent would submit an initial prior authorization request, resulting in 24,000 additional initial requests, plus the estimated CY 2026 initial requests of 232,836, for a total of 256,836 initial requests in CY 2026.

We assume that 20 percent of the estimated initial prior authorization requests received (256,836) would receive a non-affirmative decision and would resubmit their request, for a total of 51,367 level one resubmissions. We assume that subsequent resubmissions would be 10 percent of the previous level resubmission, totaling 5,137 for level 2 resubmissions, and 514 for level 3 resubmissions. In sum, we estimate the total number of submissions for Year 1 to be 256,836 initial requests plus

57,017 resubmissions for a total of 313,852 submissions. We estimate the cost of mailing medical records to be \$6,275 in Year 1. The total estimated burden for Year 1 is \$5,988,332, which includes the time associated with submitting prior authorization requests multiplied by the loaded rate of \$38.12 an hour, plus the cost of mailing records and documents.

b. Prior Authorization Process for Certain DMEPOS Items

TABLE 63: DMEPOS PRIOR AUTHORIZATION SUBMISSION BURDEN FOR YEAR 1

Activity	Estimated Responses Per Year (number of prior authorization requests submitted)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Initial Submissions	255,808	0.5	127,904	\$4,875,700
Fax and Electronic Resubmissions	56,789	0.5	28,395	\$1,082,417
Mail Initials	1,027	0.5	514	\$19,594
Mail Resubmissions	228	0.5	114	\$4,346
Mail Cost	N/A	\$5 (1,255)	N/A	\$6,275
Total	313,852	N/A	156,927	\$5,988,332

We expect an annual growth rate of 3 percent for the number of requests based on more people aging into the program and qualifying for coverage. Accordingly, in Year 2 we estimate that there would be 264,541 initial prior authorization requests from Year 1 plus and an additional 24,000 initial requests from codes that would potentially be

added to the Required Prior Authorization List in Year 2 for a total of 288,541 initial requests. Using the same rates of resubmissions described in Year 1, we estimate 64,056 resubmission requests for the total number of submissions in Year 2 of 352,597. We assume 20 percent of initial requests will be resubmitted for a level

one total of 57,708. Subsequent resubmissions would be 10 percent of the previous level resubmission, totaling 5,771 for level 2 resubmissions, and 577 for level 3 resubmissions. Accordingly, we estimate a total burden of \$6,727,543 for Year 2.

TABLE 64: TOTAL ANNUAL BURDEN

Year One	Year Two	Average Annual Burden
\$5,988,332	\$6,727,543	\$6,357,938

The annual burden for Year 1 is \$5,988,332, the annual burden for Year 2 is \$6,727,543 for an average annual burden of \$6,357,938.

The proposed provisions permit CMS to exempt suppliers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a periodic assessment. If the rate of non-payable claims submitted becomes higher than 10 percent during an

assessment, we would withdraw exemption for the specific noncompliant supplier. We assessed data from previous years to determine the number of suppliers that would have met the 90 percent compliance rate.

To assess the reduction in burden for compliant suppliers, we start by looking at the total number of provider transaction access numbers (PTANs), a

unique identification number assigned by Medicare to providers and suppliers that bill Medicare for services, submitting claims for payment and mandatory prior authorization requests. That total number for 2024 was 9,298. Of the total number of PTANs, 6 percent of those PTANs met the criteria for an exemption from mandatory prior authorization requirements, or 558 total PTANs. We are unable to determine the

number of compliant suppliers in future years. However, if we average the data from previous years, the average percentage of compliant suppliers or PTANs is 4 percent.

TABLE 65: AVERAGE EXEMPT SUPPLIERS BY YEAR

CY	Total PTAN	PTAN Who Meet Criteria	Percentage of Exempt PTAN
2022	7,049	148	2%
2023	8,048	249	3%
2024	9,298	558	6%

The total burden is assessed in Table 64. By reducing the total average annual burden (\$6,357,938) by the average number of suppliers (represented by PTANs) *not* submitting prior authorization requests by 4 percent, we have an average savings of \$254,318 per year.

7. DMEPOS Competitive Bidding Program

a. ICRs for the Submission of Financial Documents (§ 414.414(d))

The following proposed changes will be submitted to OMB for review under control number 0938–1016 (CMS–10169). When ready, the finalized changes (under the CY 2026 HH PPS final rule) will be submitted to OMB for reinstatement with the changes. We let the previously approved requirements and burden lapse as the requirements/ burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion by soliciting comment on such outdated requirements and burden.

Per § 414.414(d), each bidding entity must submit along with its bid the applicable covered documents specified in the request for bids. As discussed in section VII. of this proposed rule, based on internal review we are proposing to streamline the requirements and evaluation of the DMEPOS CBP financial standards, while still ensuring that suppliers offered contracts are financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. Specifically, CMS is proposing to only require bidding entities to submit a credit report with a numerical credit score or rating during the bid window. The submission of a tax return extract, income statement, balance sheet, and statement of cash flows would no longer be required, which would significantly reduce the time it takes a bidding entity’s Administrative Services Manager to assemble and upload financial documents during the

bidding process by minus 5 hours and 15 minutes (from 8 hours and 21 minutes to 3 hours and 12 minutes).

As a result of the decreased submission requirement CMS would no longer be able to utilize revenue data from the bidding entity’s tax return to determine if it meets the definition of a “small supplier” in the DMEPOS CBP (that is, a bidding entity that generates gross revenue of \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue). To address this, CMS is proposing to add a question to Form A (Application for DMEPOS Competitive Bidding Program) that would allow a bidding entity to attest whether it meets the definition of a small supplier.

While we do not know the exact number of bidders that would bid in the next round, for the purpose of scoring the PRA-related impact of the aforementioned changes, we expect that the number of bidders would increase by approximately 1,000 bidders (from 1,500 to 2,500 bidders) due to the proposals discussed in section VIII.B.7.b. through d. of this proposed rule. As a result, we estimate there would be approximately 833.33 bidders annually (2,500 bidders/3 years) in the next round and each bidder would complete Form A.

We expect the burden associated with the new attestation requirement to be minimal since suppliers should already be aware of their current revenue levels. That said, for the purpose of scoring the PRA-related impact of this rule’s proposed changes, we estimate that it would take (on average) 6 minutes (0.1 hr) at \$104.22/hr for a bidding entity’s Administrative Services Manager to complete the attestation question. In aggregate, we estimate an additional annual burden of 83 hours (833.33 bids/ year × 0.1 hr/bid) at a cost of \$8,650 (83 hr × \$104.22/hr) for completing the attestation in Form A.

With regard to the reduction in the number of covered documents that bidding entities are required to submit

during the bid window, we estimate 500 bidders (1,500 active bids per year/3 years) since this is the revision of an existing (active) requirement. In aggregate, we estimate an annual savings of minus 2,625 hours (500 bids × – 5.25 hr/bid) and minus \$273,578 (– 4,375 hr × \$104.22/hr) for completing Form A.

Overall, we estimate an annual savings of minus 2,542 hours (83 hr – , 2,625 hr) and minus \$264,928 (\$8,650 – \$273,578).

b. ICRs for Adjustments to Single Payment Amounts (SPAs) (§ 414.408(b))

The following proposed changes will be submitted to OMB for review under control number 0938–1016 (CMS–10169). When ready, the finalized changes (under the CY 2026 HHS PPS final rule) will be submitted to OMB for reinstatement with the changes. We let the previously approved requirements and burden lapse as the requirements/ burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion by soliciting comment on such outdated requirements/burden.

As discussed in section VII. of this proposed rule, based on internal review and industry feedback, we propose to revise § 414.408(b) which currently does not allow changes to the SPAs for the duration of a round of the DMEPOS CBP. Specifically, we propose adding an annual update factor to adjust the SPAs for the second and third year of a DMEPOS CBP contract performance period by the same annual covered item update factors applied to the fee schedule amounts for the items in non-CBAs. Therefore, when a bidding entity is formulating its bid amounts at the time of bidding and entering it on Form B (Bidding Form), a bidder would no longer need to account for inflation and/ or other potential future effects of price increases to provide certain DMEPOS.

We expect that the change would reduce the amount of time for an Administrative Services Manager to

complete Form B by approximately 24 minutes (0.4 hr) (from 3.0 hr to 2.6 hr).

While we do not know the exact number of bidders that would bid in the next round, for the purpose of scoring the PRA-related impact of the aforementioned changes, we expect that the number of bidders would increase by approximately 1,000 bidders (from 1,500 to 2,500 bidders) due to the proposals discussed in section VIII.B.7.b. through d. of this proposed rule. We also expect that the average bidder would bid in 22 competitions (our active burden estimates 35 competitions) for a difference of minus 13 competitions.

In aggregate, we estimate savings of minus 14,500 hours [CURRENT (1,500 bidders $\times$ 35 bids/bidder $\times$ 3 hr/bid) – PROPOSED (2,500 bidders $\times$ 22 bids/bidder $\times$ 2.6 hr/bid)] and minus \$1,511,190 (14,500 hr $\times$ \$104.22/hr) for completing Form B. Annually, this would amount to a savings of approximately 4,833 hours (14,500 hr/3 yr) and \$503,730 (\$1,511,190/3 yr).

c. ICRs for Determining the Number of Contracts Awarded (§ 414.414(h))

The following proposed changes will be submitted to OMB for review under control number 0938–1016 (CMS–10169). When ready, the finalized changes (under the CY 2026 HH PPS final rule) will be submitted to OMB for reinstatement with the changes. We let the previously approved requirements and burden lapse as the requirements/burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion by soliciting comment on such outdated requirements/burden.

As discussed in section VII. of this proposed rule, based on internal review we are proposing to revise § 414.414(h) for how CMS determines the number of DMEPOS CBP contracts to award to DMEPOS bidding entities. Specifically, we propose to use contract supplier utilization information from previous rounds of the DMEPOS CBP for product categories previously included in the DMEPOS CBP as well as information on current supplier utilization for new product categories. With this change, bidding entities would no longer have to

determine the capacity that they could furnish in each competition and enter the applicable capacity estimate(s) on Form B of their bid submission.

We believe it took a supplier's Administrative Services Manager approximately 90 minutes (1.5 hr) (out of 3.0 hr/bid) to determine their estimated capacity in each competition and then entering it on each Form B.

As previously mentioned, while we do not know the exact number of bidders that would bid in the next round, for purposes of scoring the PRA-related impact of this rule, we expect that the average bidder would bid in 22 competitions. While we previously estimated that the average bidder would complete 35 Form B's (5 CBAs $\times$ 7 product categories), we believe that the additional 1,000 bidders would only submit, on average, bids for approximately 2 competitions (two Form Bs) in the next round of the DMEPOS CBP, reducing the average number of Form B submissions by 13 (from 35 to 22 competitions) per bidder.

In aggregate, we estimate savings of minus 75,000 hours [CURRENT (1,500 bidders $\times$ 35 bids/bidder $\times$ 3 hr/bid) – PROPOSED (2,500 bidders $\times$ 22 bids/bidder $\times$ 1.5 hr/bid)] and minus \$7,816,500 (75,000 hr $\times$ \$104.22/hr) for completing Form B. Annually, this would amount to a savings of approximately 25,000 hours (75,000 hr/3 yr) and \$2,605,500 (\$7,816,500/3 yr).

d. ICRs for the Remote Item Delivery (RID) Competitive Bidding Program and Revising the Definition of Item Related to Medical Supplies (§ 414.402)

The following proposed changes will be submitted to OMB for review under control number 0938–1016 (CMS–10169). When ready, the finalized changes (under the CY 2026 HH PPS final rule) will be submitted to OMB for reinstatement with the changes. We let the previously approved requirements and burden lapse as the requirements/burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion by soliciting comment on such outdated requirements/burden.

As discussed in section VII. of this proposed rule, based on internal review,

under § 414.402, we are proposing to create a new definition of RID competitive bidding program to mean a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under the product category to all Medicare beneficiaries regardless of where they live in the CBA. The CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country.

As discussed in section VII. of this proposed rule, because we are also proposing to specify that ostomy, tracheostomy, and urological supplies are medical supplies mandated for inclusion under the DMEPOS CBP by section 1847(a)(2)(A) of the Act, we expect that both changes would result in an increase in burden as suppliers would potentially have additional CBAs and product categories in which they could bid.

While we do not know the exact number of bidders that would bid in the next round, for the purpose of scoring the PRA-related impact of the aforementioned changes, we expect 2,500 bidders (an increase of 1,000 bidders) due to the proposals discussed in section VIII.B.7.b. through d. of this proposed rule. As a result, we estimate there would be approximately 833.33 bidders annually (2,500 bidders/3 years) in the next round and each bidder would complete 22 Form Bs (a decrease of 13 competitions/bidder).

Because of the new competitions being added into the DMEPS CBP, we estimate that it would take a supplier's Administrative Services Manager an additional 1 hour at \$104.22/hr to develop its bid amount for each product category that they submit a bid and an additional 6 minutes (0.1 hr) to complete Form B.

In aggregate, we estimate a burden of 20,167 hours (833.33 bidders/year $\times$ 22 bids/bidder $\times$ 1.1 hr/bid) at a cost of \$2,101,805 (20,167 hr $\times$ \$104.22/hr) for completing Form B.

e. Summary of Annual Burden Estimates for DMEPOS CBP Proposed Requirements

TABLE 66: PROPOSED DMEPOS CBP ANNUAL BURDEN ESTIMATES

Regulatory Section in Title 42 of the CFR	Form	Number of Respondents	Total Number of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate (\$/hr)	Total Costs (\$)	Annualized Time (hours)	Annualized Costs (\$)
Attestation (§ 414.414(d))	Form A	833.33	833.33	0.1 hr/bid	83	104.22	8,650	83	8,650
Submission of Covered Documents (§ 414.414(d))	Form A	1,500	500	(5.25) hr/bid	(2,625)	104.22	(820,733)	(2,625)	(273,578)
Adjustments to Single Payment Amounts (§ 414.408(b))	Form B	1,000	1,000	0.4 hr/bid	(14,500)	104.22	(1,511,190)	(4,833)	(503,730)
Capacity Estimates (§ 414.414(h))	Form B	1,000	1,000	1.5 hr/bid	(75,000)	104.22	(7,816,500)	(25,000)	(2,605,500)
Develop Bid Amount (§ 414.402)	Form B	833.33	18,333	1.1 hr/bid	20,167	104.22	6,308,228	20,167	2,101,805
TOTAL	N/A	2,333 (1,500 + 833)	21,666	Varies	(71,875)	104.22	(3,831,545)	(12,208)	(1,272,353)

C. 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 requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at <https://www.cms.gov/regulations-and-guidance/legislation/paperwork-reductionactof1995/pralisting>.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–1828–P, RIN 0938–AV53), the ICR's CFR citation, and the OMB control number.

IX. Regulatory Impact Analysis

A. Statement of Need

1. HH PPS

Section 1895(b)(1) of the Act requires the Secretary to establish an HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) the computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amount be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standard prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act requires the standard prospective payment amount be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the

relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that were the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality and links the quality data submission to the annual applicable percentage increase.

Sections 1895(b)(2) and 1895(b)(3)(A) of the Act, as amended by sections 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, required the Secretary to implement a 30-day unit of payment, for 30-day periods beginning on and after January 1, 2020. Section 1895(b)(3)(D)(i) of the Act, as added by section 51001(a)(2)(B) of the BBA of 2018, requires the Secretary to annually determine the impact of differences between assumed behavior changes, as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act.

The HH PPS wage index utilizes the wage adjustment factors used by the Secretary for purposes of sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act for hospital wage adjustments.

2. HH QRP

Section 1895(b)(3)(B)(v) of the Act authorizes the HH QRP, which requires HHAs to submit data in accordance with the requirements specified by CMS. Failure to submit data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points.

3. Expanded HHVBP Model

In the CY 2022 HH PPS final rule (86 FR 62292 through 62336) and codified at 42 CFR part 484, subpart F, we finalized our policy to expand the HHVBP Model to all Medicare certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. CY 2022 was a pre-implementation year. CY 2023 was the first performance year in which HHAs individual performance on the applicable measures affects their Medicare payments in CY 2025. In this proposed rule, we include proposed changes to the expanded HHVBP Model applicable measure set and measure weights, a new measure removal factor, and a request for information (RFI) related to potential future measure concepts.

4. Updates to the Home Health Agency CoPs to Align With the OASIS All-Payer Submission Requirements

This proposed rule updates the CoPs to further clarify that the OASIS all-payer submission requirement applies to all HHA patients receiving skilled services, not only Medicare and Medicaid patients.

5. Provider Enrollment

Consistent with section 1866(j) of the Act, we are proposing several Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include, but are not limited, to: (1) adding and modifying grounds for denying, revoking, or deactivating a provider's or supplier's Medicare enrollment; and (2) expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers, which we

believe would assist in protecting the Trust Funds and Medicare beneficiaries.

6. DMEPOS Supplier Accreditation Organizations

Section 1834(a)(20) of the Act and 42 CFR 424.57 require DMEPOS suppliers to be accredited by a CMS-approved AO to enroll in and bill the Medicare program. The main purpose of accreditation is to confirm—typically via a survey of the DMEPOS supplier's location—that the supplier meets detailed quality standards involving, for example, its administration, financial management, customer service, and DMEPOS product safety. Section 424.58 outlines some of the components and requirements of the DMEPOS accreditation program. However, this regulatory section has not been updated since its promulgation in 2006. Given the ongoing problem of fraud, waste, and abuse in the DMEPOS arena—as well as the regulatory gaps that exist in § 424.58—we believe it is necessary via this proposed rule to strengthen our oversight of DMEPOS accreditation by enhancing the regulatory requirements of § 424.58.

7. DMEPOS Prior Authorization

Consistent with provisions in section 1834(a)(15) of the Act and existing authority at § 414.234 (c)(1)(ii) that permits exemption from prior authorization for certain compliant suppliers, we propose to establish guidelines for establishing an exemption and withdrawal of an exemption. Furthermore, we propose to establish notification requirements to put suppliers on notice that the exemption has either been granted or withdrawn.

8. DMEPOS Competitive Bidding Program

This proposed rule would revise the DMEPOS CBP to enhance its effectiveness in achieving the objectives of the program as mandated by section 1847(a) of the Act. This proposed rule would revise how SPAs mandated by section 1847(b)(5)(A) of the Act would be calculated and how CMS would determine the number of contracts it would award in each CBA for every product category, taking into account the ability of bidding entities (bidders) to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the CBA on a timely basis as mandated by section 1847(b)(4)(A) of the Act. This proposed rule would also apply annual inflation update factors to the SPAs. Additionally, this proposed rule would establish special payment rules for class II continuous glucose

monitors and insulin infusion pumps to pay for these items and all related supplies and accessories on a 90-day rental basis under the DMEPOS CBP. This proposed rule would classify class III continuous glucose monitors and insulin infusion pumps used in conjunction with class III continuous glucose monitors as items that require frequent and substantial servicing and make payment for the items using the same 90-day rental method and payment amounts established for class II continuous glucose monitors and insulin infusion pumps under the DMEPOS CBP. This proposed rule would also establish the definition of “remote item delivery (RID) competitive bidding area” under the DMEPOS CBP. In addition, this proposed rule would revise the methodology used to establish bid limits and address the conditions for determining when contracts cannot be awarded in accordance with section 1847(b)(2)(A)(iii) of the Act because the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. This proposed rule would also revise the definition of “item” to clarify that items that may be included in a CBP include medical supplies, including ostomy, tracheostomy, and urological supplies in accordance with section 1847(a)(2)(A) of the Act. Also, this proposed rule would streamline the requirements and evaluation of the DMEPOS CBP financial standards as well as the processes for evaluating and notifying a bidder of any applicable covered document(s) not submitted by the CDRD. In addition, this rule proposes to codify the DMEPOS CBP bid surety bond rider process. This proposed rule also proposes to add a Tribal exception to the DMEPOS CBP. This proposed rule would add a termination clause to the DMEPOS CBP supplier contracts that could be utilized during a public health emergency.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, “Regulatory Planning and Review”; Executive Order 13563, “Improving Regulation and Regulatory Review”; Executive Order 14192, “Unleashing Prosperity Through Deregulation”; the Regulatory Flexibility Act (RFA); section 1102(b) of the Social Security Act; section 202 of the Unfunded Mandates Reform Act of 1995; and Executive Order 13132, “Federalism”.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of Executive Order 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis that presents the cost and benefit of the rulemaking to the best of our ability.

C. Detailed Economic Analysis

1. Effects of the Proposed Changes for the CY 2026 HH PPS

This rule proposes to update Medicare payments under the HH PPS for CY 2026. The net transfer impact related to the changes in payments under the HH PPS for CY 2026 is estimated to be –\$1.135 billion (–6.4 percent). The \$1.135 billion decrease in estimated payments for CY 2026 reflects the effects of the proposed CY 2026 home health payment update percentage of 2.4 percent (\$425 million increase), an estimated 3.7 percent decrease that reflects the effects of the permanent adjustment (\$655 million decrease), an estimated 4.6 percent decrease that reflects the effects of the temporary adjustment (\$815 million decrease) and an estimated 0.5 percent decrease that reflects the updated FDL (\$90 million decrease).

We use the latest data and analysis available. However, we do not adjust for future changes in such variables as number of visits or case-mix. This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home

health benefit, based primarily on Medicare claims data for periods that ended on or before December 31, 2024. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that overall changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 67 represents how HHA revenues are likely to be affected by the proposed policy changes for CY 2026. For this analysis, we used an analytic file with linked CY 2024 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2024. The first column of table 67 classifies HHAs according to a number of characteristics

including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the permanent adjustment on all payments. The aggregate impact of the permanent adjustment reflected in the third column does not equal the proposed – 4.059 percent permanent adjustment because the adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The fourth column shows the payment effects of the recalibration of the case-mix weights offset by the case-mix weight budget neutrality factor. The fifth column shows the payment effects of updating the CY 2026 wage index (that is, the FY 2026 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022 (FY 2022 cost report data)) with a 5 percent cap on wage index decreases. The aggregate impact of the changes in the fifth column is zero percent, due to the wage index budget neutrality factor. The sixth column shows the payment effects of the proposed CY 2026 home health payment update percentage. The seventh column shows the payment effects of the proposed FDL. The eighth

column shows the payment effects of the temporary adjustment on all payments. The aggregate impact of the temporary adjustment reflected in the eighth column does not equal the proposed – 5 percent temporary adjustment because the adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The last column shows the combined effects of all the proposed provisions.

Overall, it is projected that aggregate payments in CY 2026 would decrease by 6.4 percent which reflects the 3.7 percent decrease from the permanent adjustment, the 4.6 percent decrease from the temporary adjustment, the 0.5 percent decrease from the updated FDL and the proposed 2.4 percent increase to the home health payment update percentage. As illustrated in table 67, the combined effects of all changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2026 wage index, the percentage of total HH PPS payments that were subject to the LUPA or paid as outlier payments, and the degree of Medicare utilization.

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TABLE 67: PROPOSED CY 2026 HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY

	Number of Agencies	Permanent Adjustment	CY 2026 Case-Mix Weights Recalibration Factor	CY 2026 Updated Wage Index (with 5% cap)	CY 2026 Proposed HH Payment Update Percentage	CY 2026 Fixed-Dollar Loss (FDL) Update	Temporary Adjustment	Total
All Agencies	9,768	-3.7%	0.0%	0.0%	2.4%	-0.5%	-4.6%	-6.4%
Facility Type and Control								
Free-Standing/Other Vol/NP	718	-3.6%	0.1%	0.5%	2.4%	-0.6%	-4.5%	-5.7%
Free-Standing/Other Proprietary	8,091	-3.7%	0.0%	-0.2%	2.4%	-0.4%	-4.6%	-6.5%
Free-Standing/Other Government	101	-3.5%	0.0%	0.0%	2.4%	-0.8%	-4.3%	-6.2%
Facility-Based Vol/NP	389	-3.4%	0.1%	0.3%	2.4%	-0.8%	-4.3%	-5.7%
Facility-Based Proprietary	24	-3.6%	0.0%	-0.9%	2.4%	-0.5%	-4.5%	-7.1%
Facility-Based Government	167	-3.6%	0.2%	0.2%	2.4%	-0.6%	-4.4%	-5.8%
Subtotal: Freestanding	8,983	-3.7%	0.0%	0.0%	2.4%	-0.4%	-4.6%	-6.3%
Subtotal: Facility-based	582	-3.4%	0.1%	0.2%	2.4%	-0.7%	-4.3%	-5.7%
Subtotal: Vol/NP	1,107	-3.5%	0.1%	0.4%	2.4%	-0.6%	-4.4%	-5.6%
Subtotal: Proprietary	8,115	-3.7%	0.0%	-0.2%	2.4%	-0.4%	-4.6%	-6.5%
Subtotal: Government	268	-3.5%	0.1%	0.1%	2.4%	-0.7%	-4.4%	-6.0%
Facility Type and Control: Rural								
Free-Standing/Other Vol/NP	164	-3.6%	0.1%	0.5%	2.4%	-0.6%	-4.4%	-5.6%
Free-Standing/Other Proprietary	787	-3.8%	-0.1%	0.0%	2.4%	-0.3%	-4.7%	-6.5%
Free-Standing/Other Government	62	-3.5%	-0.1%	1.1%	2.4%	-0.7%	-4.4%	-5.2%
Facility-Based Vol/NP	155	-3.5%	0.3%	1.1%	2.4%	-0.8%	-4.3%	-4.8%
Facility-Based Proprietary	8	-3.6%	0.2%	0.6%	2.4%	-0.6%	-4.6%	-5.6%
Facility-Based Government	120	-3.5%	0.2%	0.5%	2.4%	-0.8%	-4.3%	-5.5%
Facility Type and Control: Urban								
Free-Standing/Other Vol/NP	554	-3.6%	0.1%	0.5%	2.4%	-0.6%	-4.5%	-5.7%
Free-Standing/Other Proprietary	7,304	-3.7%	0.0%	-0.2%	2.4%	-0.4%	-4.6%	-6.5%
Free-Standing/Other Government	39	-3.4%	0.0%	-0.5%	2.4%	-0.8%	-4.3%	-6.6%
Facility-Based Vol/NP	234	-3.4%	0.1%	0.1%	2.4%	-0.8%	-4.2%	-5.8%
Facility-Based Proprietary	16	-3.7%	0.0%	-1.6%	2.4%	-0.5%	-4.5%	-7.9%
Facility-Based Government	47	-3.6%	0.3%	-0.1%	2.4%	-0.5%	-4.5%	-6.0%
Facility Location: Urban or Rural								
Rural	1,339	-3.7%	0.0%	0.2%	2.4%	-0.4%	-4.6%	-6.1%
Urban	8,429	-3.7%	0.0%	-0.1%	2.4%	-0.5%	-4.6%	-6.5%
Facility Location: Region of the Country (Census Region)								
New England	297	-3.6%	-0.1%	1.6%	2.4%	-0.5%	-4.5%	-4.7%

Mid Atlantic	367	-3.6%	0.3%	-0.3%	2.4%	-0.5%	-4.5%	-6.2%
East North Central	1,363	-3.7%	0.0%	0.7%	2.4%	-0.4%	-4.6%	-5.6%
West North Central	548	-3.6%	0.0%	1.1%	2.4%	-0.6%	-4.5%	-5.2%
South Atlantic	1,554	-3.7%	-0.1%	0.3%	2.4%	-0.4%	-4.6%	-6.1%
East South Central	357	-3.8%	-0.1%	0.1%	2.4%	-0.3%	-4.7%	-6.4%
West South Central	1,948	-3.7%	-0.1%	-0.3%	2.4%	-0.5%	-4.6%	-6.8%
Mountain	692	-3.7%	0.0%	0.1%	2.4%	-0.5%	-4.5%	-6.2%
Pacific	2,600	-3.7%	0.0%	-1.1%	2.4%	-0.5%	-4.6%	-7.5%
Outlying	42	-3.6%	1.1%	-0.1%	2.4%	-0.4%	-4.5%	-5.1%
Facility Size (Number of 30-day Periods)								
< 100 periods	2,285	-3.7%	-0.1%	-0.3%	2.4%	-0.6%	-4.5%	-6.8%
100 to 249	1,563	-3.6%	-0.1%	-0.4%	2.4%	-0.6%	-4.5%	-6.8%
250 to 499	1,773	-3.7%	-0.1%	-0.4%	2.4%	-0.5%	-4.5%	-6.8%
500 to 999	1,891	-3.7%	-0.1%	-0.3%	2.4%	-0.5%	-4.6%	-6.8%
1,000 or More	2,256	-3.7%	0.0%	0.1%	2.4%	-0.4%	-4.6%	-6.2%

Source: CY 2024 Medicare claims data for periods with matched OASIS records ending in CY2024 (as of March 13, 2025).

Notes: The estimated 3.7 percent decrease related to the proposed permanent adjustment includes all payments, while the -4.059 percent permanent adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. Similarly, the estimated 4.6 percent decrease related to the proposed temporary adjustment includes all payments, while the -5.000 percent temporary adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The "CY 2026 Updated Wage Index (with 5% cap)" column reflects a 5-percent cap on wage index decreases. The "Fixed Dollar Loss (FDL) Update" column reflects a change in the FDL from 0.35 to 0.46. Due to missing Provider of Services file information (from which home health agency characteristics are obtained), some subcategories in the impact tables have fewer agencies represented than the overall total (of 9,768); totals involving facility type (only) add up to 9,565 and totals involving control type add up to 9,490.

REGION KEY:

New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central=Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
Pacific=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

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2. Effects of the Proposed Changes for the HH QRP for CY 2027

Failure to submit HH QRP data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. For the CY 2023 program year, 820 of the 11,549 active Medicare-certified HHAs, or approximately 7.1 percent, did not receive the full annual percentage increase because they did not meet assessment submission requirements. The 820 HHAs that did not satisfy the reporting requirements of the HH QRP for the CY 2023 program year represent \$149 million in home health claims payment dollars during the reporting period out of a total \$16.4 billion for all HHAs.

This proposed rule proposes to remove four items as standardized patient assessment data elements beginning with the CY 2026 HH QRP.

The four assessment items proposed for collection are (1) Living Situation, (2) Food Runs Out, (3) Food Doesn't Last, and (4) Utilities. CMS is also proposing to remove the COVID-19 Vaccine: Percent of Patients Who Are Up to Date measure and the item related to the measure and corresponding data element. The net effect of these proposals is a decrease of four data elements at the start of care and resumption of care time points and a decrease in one data element at the transfer of care, death at home and discharge time points for a net decrease in burden.

Section VIII.B.1. of this proposed rule provides a detailed description of the net decrease in burdens associated with the proposed changes. We proposed that removal of data elements associated with the HH QRP proposals would begin with assessments as of April 1, 2026. The cost impact of these proposed changes was estimated to be a net decrease of \$17,810,282 in annualized cost to HHAs, discounted at 2 percent relative to year 2023, over a perpetual time horizon beginning in CY 2026. We described the estimated burden and cost

reductions for these measures in section VIII. of this proposed rule. In summary, the implementation of proposals outlined in this proposed rule for the HH QRP is estimated to decrease the burden on HHAs by \$1,496 per HHA annually, or \$17,810,282 for all HHAs annually.

In section III.E. of this proposed rule, we propose to amend the data non-compliance reconsideration request policy and process. For HHAs that seek to file an extension to file a request for reconsideration of a noncompliance determination, we estimate that this request will take HHAs approximately 15 minutes to complete. We believe that this data would be entered by the medical records specialists. However, HHAs determine the staffing resources necessary. For the purposes of calculating the costs we obtained median hourly wages from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates.¹⁰¹ To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 68.

TABLE 68: U.S. BUREAU OF LABOR AND STATISTICS' MAY 2024 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Other Indirect Costs and Fringe Benefits (\$/hr)	Adjusted Hourly Wage (\$/hr)
Medical Records Specialists	29-2072	\$24.16	\$24.16	\$48.32

We estimate that the collection of this request will result in an additional 15 minutes, or 0.25 hours, per request. Based on the number of reconsiderations requests we have received in the previous 3 years, we estimate an average of 85 requests per year, for an additional 21 hours per year (0.25 hours x 85 forms per year) for all HHAs. Given an estimated \$48.32 hourly wage, we estimate an increase of \$1015 (21 hours x \$48.32) for all HHAs annually or \$11.94 per HHA that request reconsiderations.

Section VIII. of this proposed rule provides a detailed description of the net decrease associated with the proposed changes. For the COVID-19 items collected at transfer of care, death at home, and discharge, we estimate a decrease in clinician cost of \$4,326,249 or \$363 (–\$4,326,249/11,904) for each

of the 11,904 active HHAs. For the four SDOH data elements removed at start of care or resumption of care, we estimate a decrease in clinician cost of \$13,484,033 or \$1,132 (–\$13,484,033/11,904) for each of the 11,904 active HHAs. For all proposals, we estimate a decrease in clinician costs of –\$17,810,282 between 2027 and 2026 related to the implementation of the proposals outlined in this proposed rule across all HHAs or a \$1,496 decrease (–\$17,810,282/11,904). Discounted at 2 percent relative to year 2023, over a perpetual time horizon beginning in CY 2026.

3. Effects of the Expanded HH VBP Model

In the CY 2022 HH PPS final rule (88 FR 77676), we estimated that the expanded HHVBP Model would

generate a total projected 5-year gross FFS savings of \$3,376,000,000. The changes to the applicable measure set proposed in this rule will not change those estimates because they do not change the number of HHAs in the Model or the payment methodology.

Based on policies discussed in this proposed rule, Tables 69 and 70 display the distribution of possible unweighted payment adjustments¹⁰² using CY 2023 as the performance year and CY 2022 as the baseline year for all 1-year measures. For 2-year measures (such as DTC and MSPB-PAC), payment adjustments were calculated using CYs 2022 and 2023 as the performance period and CYs 2021 and 2022 as the baseline period. Note that payment adjustments in the expanded Model are made in a budget-neutral manner.

¹⁰¹ U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates. https://www.bls.gov/oes/current/oes_nat.htm

¹⁰² Payment adjustments calculated for all HHAs with Medicare certification dates prior to January 1, 2021.

Tables 69 and 70 show the value-based incentive payment adjustments for the estimated 7,061 HHAs that would qualify to compete in the expanded Model based on CY 2023 performance data stratified by volume-based cohort, as defined in section III.F. of the CY 2022 HH PPS final rule (86 FR 62312). Using CY 2023 performance year data and the 5 percent payment adjustment, based on the 11 proposed quality measures, the 6,391 HHAs in the larger-volume cohort would have an average payment adjustment of positive 0.004 percent (+0.004 percent). Overall, smaller-volume HHAs would have an average payment adjustment of positive 0.006 percent (+0.006 percent). Eighteen states/territories do not have any HHAs in the smaller-volume cohort. The remaining states/territories have HHAs in both volume-based cohorts. Florida, for example, has 556 HHAs in the larger-volume cohort with an average payment adjustment of positive 0.289 percent (+0.289 percent) and 50 HHAs in the smaller-volume cohort with an average payment adjustment of negative 0.003 percent (– 0.003 percent).

The next columns provide the distribution of payment adjustment by percentile. For example, 10 percent of HHAs in the larger-volume cohort would receive downward payment adjustments of more than negative 2.252

percent (– 2.252 percent). The median (50th percentile) payment adjustment for the larger-volume cohort is negative 0.086 percent (– 0.086 percent). Among smaller-volume HHAs, 10 percent of HHAs would receive downward payment adjustments of more than negative 2.513 percent (– 2.513 percent). The median (50th percentile) payment adjustment for the smaller-volume cohort is negative 0.094 percent (– 0.094 percent). As an example of the range of payment adjustments in a given state, payment adjustments for larger-volume HHAs in Florida range from negative 2.284 percent (– 2.284 percent) at the 10th percentile to positive 2.945 percent (+2.945 percent) at the 90th percentile, while the median (50th percentile) payment adjustment is positive 0.211 percent (+0.211 percent).

Table 71 provides the payment adjustment distribution based on the proportion of dual-eligible beneficiaries, average case mix using Hierarchical Condition Category (HCC) scores, proportion of beneficiaries that reside in rural areas, and HHA organizational status. To define cutoffs for the “percentage of dual eligible beneficiaries,” low through high percentage dual-eligible are based on the 20th, 40th, 60th, and 80th percentiles of percent dual eligible beneficiaries, respectively, across HHAs

in CY 2021. To define case mix cutoffs, low, medium, or high acuity are based on less than the 25th percentile, between the 25th and 75th percentiles, and greater than the 75th percentile of average HCC scores, respectively, across HHAs in CY 2021. To define cutoffs for percentage of rural beneficiaries, all non-rural, up to 50 percent rural, and over 50 percent rural are based on the home health beneficiaries’ core-based statistical area (CBSA) urban versus rural designation. Based on CY 2021 data, HHAs with the highest proportion of dual-eligible beneficiaries served have the highest average payment adjustment (+0.228 percent). In addition, a higher proportion of rural beneficiaries served is associated with better performance. Specifically, HHAs serving over 50 percent rural beneficiaries have an average payment adjustment of positive 0.167 percent (+0.167 percent), compared to a slightly negative average payment adjustment for HHAs serving only non-rural beneficiaries or HHAs serving up to 50 percent rural beneficiaries. Among organizational types, proprietary HHAs have a slightly negative average payment adjustment of 0.047 (– 0.047 percent), whereas HHAs in other organizational type categories have a positive average payment adjustment.

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**TABLE 69: PAYMENT ADJUSTMENT DISTRIBUTION BY VOLUME-BASED
COHORT: LARGE-VOLUME COHORT**

Larger-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	10	(0.692)	(2.830)	(2.112)	(1.518)	(0.908)	(0.515)	(0.378)	0.252	0.793	1.152
AL	111	0.418	(1.536)	(0.798)	(0.195)	0.189	0.406	0.827	1.259	1.609	2.008
AR	88	0.265	(2.237)	(0.893)	(0.484)	(0.079)	0.327	0.648	1.063	1.473	2.495
AZ	116	(0.503)	(2.731)	(1.966)	(1.350)	(0.993)	(0.392)	(0.098)	0.309	0.721	1.863
CA	1070	0.207	(2.411)	(1.636)	(1.116)	(0.507)	0.054	0.601	1.308	2.042	3.073
CO	99	(0.219)	(2.294)	(1.669)	(1.232)	(0.810)	(0.387)	0.194	0.655	1.185	2.408
CT	62	(0.240)	(2.822)	(1.892)	(1.063)	(0.446)	0.051	0.291	0.566	1.253	2.044
DC	9	(0.759)	(2.201)	(2.067)	(1.806)	(1.315)	(1.106)	(0.800)	(0.234)	0.244	2.452
DE	12	(0.160)	(1.285)	(1.176)	(1.076)	(0.868)	(0.776)	(0.564)	0.341	0.364	1.394
FL	566	0.289	(2.284)	(1.366)	(0.898)	(0.300)	0.211	0.699	1.358	2.088	2.945
GA	95	(0.650)	(2.314)	(1.934)	(1.363)	(0.921)	(0.555)	(0.314)	(0.030)	0.354	0.998
GU	3	(2.536)	(3.294)	(3.294)	(3.294)	(2.830)	(2.830)	(2.830)	(1.485)	(1.485)	(1.485)
HI	11	(1.012)	(3.015)	(2.250)	(1.995)	(1.191)	(0.969)	(0.550)	(0.384)	0.019	0.187
IA	85	0.463	(1.554)	(1.143)	(0.672)	0.066	0.516	0.880	1.464	1.872	2.544
ID	44	0.072	(1.840)	(1.126)	(0.881)	(0.078)	0.146	0.358	0.713	1.723	1.839
IL	338	(0.010)	(2.199)	(1.601)	(1.018)	(0.519)	(0.099)	0.421	0.857	1.395	2.364
IN	116	0.071	(2.039)	(1.552)	(0.875)	(0.529)	0.007	0.525	0.900	1.400	2.435
KS	77	0.032	(2.205)	(1.524)	(0.903)	(0.438)	0.105	0.640	1.018	1.522	2.056
KY	85	0.563	(1.154)	(0.775)	(0.239)	0.090	0.605	0.930	1.244	1.727	2.411
LA	160	0.174	(1.994)	(1.319)	(0.658)	(0.127)	0.207	0.674	0.981	1.527	2.072
MA	105	0.079	(2.389)	(1.538)	(1.075)	(0.544)	(0.042)	0.381	1.058	1.506	2.705
MD	49	0.264	(1.965)	(1.442)	(0.913)	(0.074)	0.303	0.592	0.972	1.829	2.529
ME	18	0.792	(0.686)	(0.232)	(0.012)	0.374	0.771	1.050	1.536	1.592	2.568
MI	230	0.270	(1.912)	(1.273)	(0.806)	(0.384)	0.153	0.603	1.107	1.625	2.702
MN	85	(0.154)	(2.277)	(1.788)	(1.267)	(0.547)	(0.104)	0.278	0.742	1.000	2.059
MO	101	0.340	(2.003)	(1.005)	(0.592)	(0.238)	0.082	0.666	1.132	2.066	2.900
MS	42	0.245	(1.056)	(0.580)	(0.165)	0.293	0.530	0.599	0.950	1.038	1.389
MT	17	(1.066)	(2.883)	(2.610)	(2.231)	(1.929)	(1.562)	(0.684)	(0.457)	0.521	1.327
NC	146	(0.246)	(1.950)	(1.255)	(0.849)	(0.561)	(0.320)	(0.124)	0.384	0.695	1.380
ND	13	(0.186)	(2.271)	(1.868)	(1.384)	(0.467)	(0.257)	0.014	1.027	1.193	1.971

Larger-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
NE	44	0.185	(1.775)	(1.357)	(0.757)	(0.470)	(0.053)	0.879	1.221	1.712	2.152
NH	19	0.037	(1.689)	(0.986)	(0.807)	(0.383)	0.200	0.602	0.730	0.888	1.617
NJ	39	0.559	(0.674)	(0.269)	(0.206)	0.089	0.566	0.904	1.057	1.423	1.969
NM	58	(0.432)	(2.325)	(1.425)	(1.188)	(0.875)	(0.522)	(0.027)	0.331	0.510	1.577
NV	101	(0.092)	(2.513)	(1.895)	(1.400)	(1.090)	(0.445)	0.212	0.769	1.791	2.853
NY	94	0.193	(1.671)	(1.253)	(0.850)	(0.533)	0.010	0.454	0.736	1.660	2.713
OH	226	(0.170)	(2.424)	(1.838)	(1.367)	(0.765)	(0.368)	0.233	0.801	1.377	2.538
OK	175	(0.379)	(2.310)	(1.782)	(1.263)	(0.821)	(0.487)	(0.110)	0.414	0.945	1.622
OR	41	(0.540)	(2.079)	(1.839)	(1.386)	(1.041)	(0.831)	(0.243)	(0.029)	0.329	1.889
PA	179	0.041	(1.835)	(1.200)	(0.665)	(0.266)	(0.031)	0.376	0.666	1.317	1.719
PR	35	(1.647)	(3.394)	(2.891)	(2.693)	(2.425)	(2.226)	(1.937)	(1.697)	(0.392)	0.575
RI	18	0.575	(1.414)	(0.614)	(0.042)	0.198	0.413	0.761	1.321	1.973	2.648
SC	65	0.162	(1.555)	(1.064)	(0.526)	(0.109)	0.097	0.399	0.679	1.087	1.674
SD	19	1.458	(0.332)	(0.169)	0.018	0.445	0.942	1.564	2.535	3.668	4.333
TN	109	0.146	(1.941)	(1.115)	(0.537)	(0.072)	0.167	0.432	0.860	1.280	2.055
TX	778	(0.425)	(2.500)	(1.981)	(1.505)	(1.084)	(0.549)	(0.130)	0.409	1.106	1.864
UT	61	0.985	(1.701)	(1.015)	(0.219)	0.237	0.928	1.553	2.001	2.769	4.004
VA	168	(0.329)	(2.303)	(1.760)	(1.290)	(0.899)	(0.378)	(0.118)	0.377	1.075	2.034
VI	1	0.182	0.182	0.182	0.182	0.182	0.182	0.182	0.182	0.182	0.182
VT	10	(1.084)	(2.084)	(1.698)	(1.569)	(1.343)	(1.182)	(1.076)	(0.807)	(0.207)	0.223
WA	58	(0.369)	(2.245)	(1.661)	(1.477)	(1.078)	(0.379)	(0.125)	0.256	1.119	2.144
WI	66	0.327	(1.450)	(1.145)	(0.649)	(0.376)	0.303	1.133	1.369	1.698	2.560
WV	45	0.025	(2.400)	(1.470)	(0.610)	(0.127)	0.246	0.502	0.819	1.080	1.660
WY	19	(0.217)	(2.396)	(1.363)	(1.155)	(0.688)	(0.404)	0.156	0.727	0.951	2.180
ALL	6,391	0.004	(2.252)	(1.570)	(1.058)	(0.539)	(0.086)	0.364	0.862	1.509	2.414

**TABLE 70: PAYMENT ADJUSTMENT DISTRIBUTION BY VOLUME-BASED
COHORT: SMALL-VOLUME COHORT**

Smaller-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	1	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)
AL	1	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)
AR	2	1.219	1.162	1.162	1.162	1.162	1.219	1.275	1.275	1.275	1.275
AZ	4	(0.800)	(2.776)	(2.776)	(2.345)	(2.345)	(2.158)	(1.970)	(1.970)	3.890	3.890
CA	209	0.244	(2.430)	(1.712)	(0.956)	(0.360)	0.139	0.639	1.355	2.205	2.921
CO	7	(0.565)	(4.699)	(3.813)	(0.908)	(0.908)	(0.383)	1.234	1.234	1.369	3.243
CT	0	-	-	-	-	-	-	-	-	-	-
DC	0	-	-	-	-	-	-	-	-	-	-
DE	1	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)
FL	50	(0.003)	(2.685)	(2.229)	(1.601)	(0.944)	0.029	0.468	1.141	2.231	2.836
GA	0	-	-	-	-	-	-	-	-	-	-
GU	0	-	-	-	-	-	-	-	-	-	-
HI	0	-	-	-	-	-	-	-	-	-	-
IA	11	1.412	(0.843)	(0.264)	0.565	1.200	1.766	2.082	2.176	2.771	3.237
ID	0	-	-	-	-	-	-	-	-	-	-
IL	60	0.361	(2.255)	(1.486)	(0.957)	(0.597)	(0.019)	0.788	1.287	2.089	3.443
IN	12	(0.606)	(2.826)	(2.608)	(1.733)	(1.256)	(0.579)	(0.025)	0.283	0.410	1.829
KS	3	2.566	2.257	2.257	2.257	2.456	2.456	2.456	2.984	2.984	2.984
KY	0	-	-	-	-	-	-	-	-	-	-
LA	2	(1.843)	(2.945)	(2.945)	(2.945)	(2.945)	(1.843)	(0.741)	(0.741)	(0.741)	(0.741)
MA	5	(0.883)	(3.391)	(2.247)	(1.103)	(1.059)	(1.014)	(0.613)	(0.212)	0.547	1.305
MD	0	-	-	-	-	-	-	-	-	-	-
ME	0	-	-	-	-	-	-	-	-	-	-
MI	41	0.692	(1.816)	(0.776)	(0.039)	0.208	0.696	1.088	2.103	2.371	2.934
MN	5	0.241	(2.098)	(1.511)	(0.924)	(0.847)	(0.770)	0.804	2.377	2.500	2.622
MO	4	0.695	0.132	0.132	0.467	0.467	0.663	0.858	0.858	1.323	1.323

Smaller-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
MP	1	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)
MS	0	-	-	-	-	-	-	-	-	-	-
MT	2	(0.810)	(0.913)	(0.913)	(0.913)	(0.913)	(0.810)	(0.707)	(0.707)	(0.707)	(0.707)
NC	3	(0.260)	(1.583)	(1.583)	(1.583)	(0.060)	(0.060)	(0.060)	0.864	0.864	0.864
ND	0	-	-	-	-	-	-	-	-	-	-
NE	6	(1.046)	(3.063)	(2.555)	(2.555)	(1.707)	(1.569)	(1.430)	0.075	0.075	2.405
NH	2	(0.654)	(1.636)	(1.636)	(1.636)	(1.636)	(0.654)	0.328	0.328	0.328	0.328
NJ	0	-	-	-	-	-	-	-	-	-	-
NM	1	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)
NV	15	(0.214)	(1.985)	(1.959)	(1.067)	(0.510)	(0.242)	(0.075)	0.462	0.842	1.914
NY	3	0.150	(2.442)	(2.442)	(2.442)	0.309	0.309	0.309	2.582	2.582	2.582
OH	12	(0.069)	(2.573)	(1.741)	(0.555)	(0.190)	(0.064)	0.276	0.349	1.571	1.632
OK	12	(0.852)	(2.373)	(1.560)	(1.451)	(1.331)	(1.197)	(0.661)	(0.466)	(0.424)	(0.307)
OR	1	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)
PA	12	(0.380)	(2.461)	(2.016)	(1.845)	(0.706)	(0.559)	(0.349)	0.343	1.879	1.892
PR	0	-	-	-	-	-	-	-	-	-	-
RI	0	-	-	-	-	-	-	-	-	-	-
SC	0	-	-	-	-	-	-	-	-	-	-
SD	1	3.442	3.442	3.442	3.442	3.442	3.442	3.442	3.442	3.442	3.442
TN	1	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)
TX	150	(0.536)	(2.795)	(2.250)	(1.827)	(1.221)	(0.741)	0.063	0.661	1.203	1.810
UT	8	0.487	(2.776)	(1.032)	(0.454)	0.047	0.355	0.662	0.775	3.169	3.503
VA	14	0.207	(2.286)	(1.428)	(0.724)	(0.670)	(0.104)	0.827	1.007	1.915	2.840
VI	0	-	-	-	-	-	-	-	-	-	-
VT	0	-	-	-	-	-	-	-	-	-	-
WA	0	-	-	-	-	-	-	-	-	-	-
WI	2	2.769	1.757	1.757	1.757	1.757	2.769	3.780	3.780	3.780	3.780
WV	3	0.353	(0.286)	(0.286)	(0.286)	0.023	0.023	0.023	1.322	1.322	1.322
WY	3	(0.229)	(1.022)	(1.022)	(1.022)	(0.734)	(0.734)	(0.734)	1.070	1.070	1.070
ALL	670	0.006	(2.513)	(1.938)	(1.177)	(0.684)	(0.094)	0.504	1.083	1.874	2.772

TABLE 71: HHVBP PAYMENT ADJUSTMENT DISTRIBUTION BY HHA CHARACTERISTICS

HHA Characteristics	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
Percentage Dual-eligible											
1st Quintile: % Dual-eligible	1,407	0.122	(2.221)	(1.523)	(1.026)	(0.431)	0.040	0.520	1.058	1.668	2.611
2nd Quintile: % Dual-eligible	1,407	0.033	(2.064)	(1.368)	(0.805)	(0.380)	0.014	0.412	0.840	1.354	2.122
3rd Quintile: % Dual-eligible	1,407	(0.060)	(2.089)	(1.442)	(0.955)	(0.519)	(0.104)	0.330	0.733	1.331	2.028
4th Quintile: % Dual-eligible	1,407	(0.317)	(2.459)	(1.932)	(1.398)	(0.938)	(0.466)	0.032	0.579	1.198	2.038
5th Quintile: % Dual-eligible	1,407	0.228	(2.525)	(1.733)	(1.101)	(0.507)	0.057	0.602	1.355	2.228	3.319
Acuity (HCC)											
1-Lowest Acuity	1,750	0.286	(2.430)	(1.675)	(1.038)	(0.415)	0.160	0.739	1.406	2.193	3.304
2-Medium Acuity	3,498	(0.062)	(2.234)	(1.555)	(1.063)	(0.554)	(0.103)	0.329	0.781	1.367	2.138
3-Highest Acuity	1,749	(0.130)	(2.232)	(1.572)	(1.076)	(0.628)	(0.237)	0.195	0.654	1.266	2.135
% Rural Beneficiaries											
1-All non-rural	3,804	(0.018)	(2.459)	(1.791)	(1.205)	(0.691)	(0.178)	0.349	0.899	1.666	2.698
2-Up to 50% rural	1,991	(0.059)	(2.151)	(1.481)	(0.979)	(0.503)	(0.102)	0.305	0.727	1.281	2.009
3-Over 50% rural	1,228	0.167	(1.920)	(1.261)	(0.755)	(0.304)	0.087	0.583	1.070	1.584	2.330
Organizational Type											
1-Vol Non-Profit-Religious	258	0.508	(1.767)	(1.034)	(0.301)	0.087	0.513	0.858	1.467	2.008	2.811
2-Vol Non-Profit-Private	521	0.089	(1.952)	(1.374)	(0.913)	(0.479)	(0.042)	0.436	0.893	1.500	2.455
3-Vol Non-Profit-Other	417	0.105	(1.929)	(1.247)	(0.768)	(0.273)	0.050	0.484	1.059	1.443	2.058
4-Proprietary	5,601	(0.047)	(2.350)	(1.700)	(1.150)	(0.632)	(0.156)	0.320	0.838	1.503	2.480
5-Govt-State/County	146	0.259	(1.674)	(1.211)	(0.688)	(0.259)	0.099	0.599	1.070	1.580	2.435
6-Govt-Govt & Voluntary	11	0.497	(0.735)	(0.357)	(0.279)	(0.055)	0.075	0.269	0.314	1.589	2.392
7-Govt-Local	91	0.270	(1.770)	(1.071)	(0.647)	(0.314)	0.491	0.669	1.038	1.748	2.308

Notes:

- Dual: low, medium, high are based on 25th and 75th percentiles of the percent of Medicare fee-for-service beneficiaries with any dual indicated across all HHAs in 2021.
- HCC Score Acuity: low, medium, high are based on 25th and 75th percentiles of the average HCC of Medicare fee-for-service beneficiaries across all HHAs in 2021.
- Percentage rural Medicare fee-for-service beneficiaries: based on CBSA of beneficiaries' ZIP code aggregated to the HHA level in 2021.

The total number of HHAs differ by category due to missing HHAs in some data sources.

across all HHAs in 2021.—*HCC Score Acuity*: low, medium, high are based on 25th and 75th percentiles of the average HCC of Medicare fee-for-service beneficiaries across all HHAs in 2021.—*Percentage rural Medicare fee-for-service beneficiaries*: based on CBSA of beneficiaries' ZIP code aggregated to the HHA level in 2021. The total number of HHAs differ by category due to missing HHAs in some data sources.

4. Updates to the Home Health Agency CoPs to Align With the OASIS All-Payer Submission Requirements

As discussed in section V. of this proposed rule, we are proposing technical revisions to the HH CoPs to further clarify that the existing requirement for reporting OASIS information applies to all HHA patients receiving skilled services. This technical change seeks to provide clarity by creating alignment between the terminology used in the CoPs and requirements for data collection and submission to OASIS for purposes of the HH QRP. It does not propose any revisions to the specific requirements for submitting data to OASIS and does not have any bearing on the change to expand the data collected that was finalized in the CY 2023 HH PPS final rule (87 FR 66862). Therefore, this technical change would not result in an increase in costs for HHAs. For a review of the burden and operational costs associated with the transition to the OASIS all-payer submission requirements we refer readers to the CY 2023 HH PPS final rule "Collection of Information" section (88 FR 66877) and to the CY 2024 HH PPS final rule for the latest burden estimates (88 FR 77676).

5. Provider Enrollment

As previously noted, we are proposing several provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. This RIA addresses provisions that: (1) we believe would have a financial impact; and (2) would not, in our view, have such an impact but which require explanation.

a. Retroactive Revocations

Section 424.535(g)(1) states that except as described in § 424.535(g)(2) and (3), a revocation becomes effective 30 days after CMS or its contractor mails notice of its determination to the provider. Under existing

§ 424.535(g)(2)(i) through (viii), there are grounds for which CMS can revoke a provider's enrollment retroactively to the date the provider's non-compliance commenced. Retroactive revocation allows CMS to collect monies that have been paid to the provider since the beginning of its non-compliance. We explained in section VI.A. of this proposed rule that we are proposing to increase significantly the number of grounds for a retroactive revocation in new § 424.535(a)(8)(iii) and (g)(2)(viii) through (xiv). These nine situations and our proposed revocation effective dates (listed in parentheses) are as follows:

- An independent diagnostic testing facility's (IDTF's) liability insurance lapsed (date the insurance lapsed).
- The provider submitted false or misleading information on its enrollment application (date the provider signed the application's certification statement).
- The provider failed to timely report a change of ownership, an adverse legal action, or addition, deletion, or change of a practice location (day after the date by which the provider was required to report the change, addition, or deletion).
- The provider's Drug Enforcement Administration (DEA) certificate of registration was surrendered in response to a show cause order (date the certificate was surrendered).
- The individual's ability to prescribe one or more drugs has been suspended or revoked by any state in which the physician or non-physician practitioner practices (date of the state's suspension or revocation).
- Under § 424.535(i), if we revoke a provider's enrollment, we can revoke all of the provider's other enrollments. The effective dates of these other revocations would be the effective date of the triggering revocation.
- A DMEPOS supplier was revoked for non-compliance with a condition or standard in § 424.57(b) or (c), such as the requirement to meet the DMEPOS quality standards (date on which the non-compliance began).
- Under § 424.535(a)(8)(i), the provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service (the earliest date of service on the claim or claims that is or are triggering the revocation).
- Under § 424.535(a)(8)(ii), CMS determines that the provider or supplier has a pattern or practice of submitting

claims that fail to meet Medicare requirements (the last date of service on the claims in question).

Table 72 contains several data categories. One is the average annual number of revocations that occur in each of the previous scenarios. Another is the average length of time between when the non-compliance begins in these situations and 30 days after the revocation letter is sent to the provider in question. For instance, suppose a provider undergoes a change of ownership effective May 1 but fails to report it to CMS. The revocation letter is mailed to the provider on June 1, meaning the effective date is July 1. The period between the date of non-compliance and the effective date under paragraph (g)(1) is thus 60 days. However, under our proposal the provider would be ineligible for payments for services furnished during this 60-day period because its revocation would now be retroactive.

An additional category addresses the amount of savings that would accrue to the Medicare program from our proposal. Based on internal CMS data, we calculated in the fourth column in Table 72 the average amount of actual payments made to each of the providers in each of the table's nine revocation reasons in Table 72 during the estimated time period in the table's third column. We then multiplied this figure by the numbers in the second column (average annual number of revocations). The fifth and final column outlines the total annual savings that would result. To illustrate—

- There are 11 revocations per year for lapses in IDTF liability insurance.
- As shown in the fourth column of the table, each of these 11 IDTFs received an average of \$19,423 during the 3-month period identified in the third column of the chart.
- Multiplying 11 by \$19,423 results in \$213,653 in total, combined annual savings for that category of revoked providers.

We recognize that in certain prior provider enrollment regulations, we have used a standard \$50,000 average annual payment amount when calculating savings figures. However, the totals in the third column of the table reflect the actual amounts the revoked providers were paid. They are accordingly much more accurate than a base \$50,000 figure.

TABLE 72: RETROACTIVE REVOCATION GROUNDS

New Retro Revocation Basis	Number of Revocations Per Year	Estimated Length of Time Between When the Non-Compliance Occurs and 30 Days After the Revocation Letter is Sent	Based Average Payments Made to Revoked Enrollment During Estimated Non-Compliance Time Period	Estimated Total Annual Savings (Number of Revocations x Average Payments)
IDTF's liability insurance lapsed	11	3 months (0.25 years)	19,423	213,653
Provider submits false/misleading information on application	31	6 months (0.5 years)	225,824	7,000,544
Provider failed to timely report change of ownership, adverse action or practice location	461	6 months (0.5 years)	1,321,736	609,320,296
Provider's DEA certificate is suspended, revoked, or surrendered in response to show cause order OR State suspends or revokes individual's ability to prescribe	7	60 days (0.164 years)	79,227	554,589
Revocation resulting in other revocations under § 424.535(i).	3	60 days (0.164 years)	281,756	845,268
DMEPOS supplier revoked for non-compliance with condition or standard in 424.57(b) or (c).	790	3 months (0.25 years)	488,328	385,779,120
§ 424.535(a)(8)(i)	9	1 year	18,371,237	165,341,133
§ 424.535(a)(8)(ii)	130	60 days (0.164 years)	7,910,366	1,028,347,580
TOTALS & AVERAGES	1,442 Per Year	Varies	28,697,897	2,197,402,183

We accordingly project annual savings of \$2,197,402,183 stemming from our retroactive revocation proposals.

b. Expanded and Clarified Revocation Reasons

In accordance with existing § 424.535(a)(14), CMS can revoke a physician's or practitioner's enrollment if the individual has a pattern or practice of prescribing Part B or D drugs that is abusive, threatens the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements. We are proposing to expand this authority to include drugs associated with services covered under Part A. We are unable to establish a savings estimate for this revision, for we cannot predict the number of instances in which we would utilize § 424.535(a)(14) for Part A prescribing patterns or practices.

We are also proposing in new § 424.535(a)(8)(i)(D) to clarify that our revocation authority under paragraph (a)(8)(i) includes situations where beneficiary attestations state that the service(s) or item(s) the provider claims were furnished to the beneficiary were,

in fact, not. As this is merely an elucidation of our existing authority to revoke in such situations, we do not anticipate additional savings therefrom.

c. Additional Deactivation Reason

We are proposing under new § 424.547 that CMS may deactivate a physician's or non-physician's practitioner's ability to order, certify, or refer the Medicare services and items identified in § 424.507(a) and (b) if the individual—

- Is enrolled in Medicare solely to order, certify, or refers beneficiaries for Medicare Part A or B services or items; *and*
- The individual has not been listed as the ordering, certifying, or referring individual on a Medicare Part A or B claim received in the previous 12 consecutive calendar months.

As with our proposed expansion of § 424.535(a)(14), we are unable to establish a savings or burden estimate for new § 424.547 because we cannot predict the number of instances in which we would apply this authority.

6. DMEPOS Supplier Accreditation Organizations

Section VI.B. of this proposed rule outlines our proposed revisions to §§ 424.57 and 424.58 and the reasons for them. Most of our changes would involve: (1) additional requirements an organization must meet to become and remain a CMS-approved DMEPOS AO; and (2) additional surveys that must be performed. The ICR component of these requirements was addressed in section VIII. of this proposed rule. This RIA discusses the principal non-ICR costs and potential savings associated with our proposals.

a. Costs

For purposes of our cost calculations, we will use the following median wage categories and hourly rates from the BLS May 2024 National Occupational Employment and Wage Estimates for all salary estimates. We believe these occupational classifications, some of which were used in the February 15, 2024, proposed rule referenced in section VI.B. of the subject rule, would be most applicable to our cost impact analysis:

TABLE 73: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Registered Nurses	29-1141	45.00	45.00	90.00
Medical and Health Services Managers (MHSM)	11-9111	56.71	56.71	113.42
Other Healthcare Practitioners and Technical Occupations (OHPTO)	29-9000	30.20	30.20	60.40
Office and Administrative Support Workers, All Other	43-9199	22.14	22.14	44.28

There are generally two types of surveys that will form the bases of our calculations: (1) initial and reaccreditation surveys (which include the survey and the accreditation); and (2) “off-cycle” surveys, or ad-hoc surveys performed outside of the initial and reaccreditation process to reconfirm compliance with the quality standards. Ad-hoc surveys—which, except perhaps in cases where the supplier is adding a new product, typically does not involve the accreditation process itself but only the survey—can occur in response to, for instance, a complaint or a CMS request that a survey be performed. The hour burdens and fees associated with (1) and (2) vary widely among AOs. However, based on our information, we estimate the following, emphasizing that: (1) the hour burdens could involve multiple individuals (for example, a 6-hour burden could have two individuals contributing 3 hours each); (2) the survey costs to the AO include travel and other expenses; and (3) both the hour and cost burdens could include incidental tasks (for example, the AO contacts the supplier for additional data regarding its reaccreditation application):

• *Initial and Reaccreditation Processes and Surveys*

++ Burden to Supplier for Initial Accreditation and Survey—24 hours and \$5,000 fee the supplier pays to the AO.

++ Burden to Supplier for Reaccreditation and Survey—14 hours and \$3,000 fee.

(Note that the two preceding burdens include the supplier’s preparation and submission to the AO of its accreditation or reaccreditation materials.)

++ Burden to AO for Survey, Review/Decision, and Accreditation (Initials and Reaccreditation)—20 hours.

• *Off-Cycle Surveys.*

++ Burden to Supplier for Survey—6 hours and \$2,000 cost of the survey.

++ Burden to AO for Survey and Review/Decision—14 hours (cost addressed below).

These figures will be used as inputs for the succeeding estimates.

There is also variance among the DMEPOS AOs regarding the staff that performs the surveys and accreditation reviews. We recognize that many DMEPOS AOs hire contractors to conduct surveys and that non-medical personnel at the AO might make final accreditation decisions. Yet we also wish to remain as consistent as possible with wage categories in other CMS accreditation rulemaking efforts. For purposes of this RIA and our burden calculations only, therefore, we will assume that: (1) contractor personnel (under the OHPTO wage category) would perform the surveys; and (2) nurses and MHSMs would perform initial reviews and make final determinations regarding the supplier’s accreditation. As for the suppliers themselves, we believe that administrative personnel would work with the AO in the survey and be involved in the accreditation process (for example, preparing the application, as they do with Form CMS–855 enrollment applications).

There are five categories of surveys, reviews, and accreditations that form the bases of our accreditation cost estimates: (1) complaint investigations and surveys; (2) additional initial surveys; (3) annual reaccreditations and surveys; (4) CMS-directed ad-hoc surveys; and (5) change of ownership surveys. These will be addressed in the succeeding subsections.

(1) Complaint Investigations and Surveys

Proposed new § 424.58(e)(3)(i)(B) and (C), state, respectively, that after receiving a complaint, an AO must—

• Perform an initial review of the complaint to determine whether, based on the complaint and any other information, the supplier may be non-compliant with one or more DMEPOS quality standards; and

• Conduct a survey of the accredited facility if the AO’s initial review concludes that such non-compliance

may exist and a survey is deemed necessary.

In assessing potential ICR costs to the AO, we estimated that each year an AO would report 50 complaints to us. With 8 AOs, this would result in 400 complaints annually. We further assume the following:

• It would take an average of 4 hours for an AO to perform its initial review of potential non-compliance. The hourly rate of this task would be split between nurses and MHSMs, resulting in a wage of \$101.71 (\$90.00 + \$113.42)/2).

• Roughly 20 percent of initial reviews would result in an off-cycle survey, which would take the OHPTO 8 hours to perform; this would also result in 80 complaint surveys being performed each year (400 × 0.2).

• It would take the AO 6 hours to render a decision on the survey and whether the supplier should remain accredited (as well as to notify the supplier of the decision). We will apply the aforementioned combined \$101.71 hourly rate for this task.

• The supplier would incur a burden of 6 hours during the survey. The hourly rate would be \$44.28.

• The cost of the complaint survey would be \$2,000, which the supplier would pay to the AO.

Given these assumptions, we project the following annual figures for complaint surveys:

• Initial Review Burden to AOs—1,600 hours and \$132,426 (400 complaints × 4 hours × \$101.71).

• Survey Cost Burden to AOs—640 hours and \$35,208 (80 surveys × 8 hours × \$60.40).

• Post-Survey Decision Burden to AOs—480 hours and \$42,566 (80 × 6 hours × \$94.59).

• Burden to Suppliers During Survey—480 hours and \$18,702 (80 × 6 × \$44.28).

• Supplier Survey Fees Paid to AO—\$150,000 (80 × \$2,000).

Table 74 outlines the annual burden impact of § 424.57(e)(3)(i)(B) and (C).

TABLE 74: ANNUAL BURDEN OF COMPLAINT INVESTIGATIONS AND SURVEYS

BURDEN TO AO				
Task	Hour Burden Per Task	Total Hours	Wage (\$)	Total Cost (\$)
AO Burden - Initial Review of Complaint	4	1,600	101.71	162,736
AO Burden - Survey	8	640	60.40	38,656
AO Burden - Post-Survey Review/Decision	6	480	101.71	48,821
Survey Fee Collections	N/A	N/A	N/A	(150,000)
TOTAL	18	2,720	Varies	100,213
BURDEN TO SUPPLIER				
Burden to Supplier During Survey	6	480	44.28	21,254
Survey Fee	N/A	N/A	N/A	150,000
TOTAL	6	480	N/A	171,254
COMBINED NET BURDEN	24	3,200	N/A	271,467

(2) Additional Surveys and Reaccreditations

Several other provisions would increase the frequency of surveys to be performed and/or reaccreditations to be undertaken:

- Proposed § 424.58(e)(8)(i)(A) states that except as otherwise directed or permitted by CMS, the AO must perform a survey of all suppliers and their locations seeking initial accreditation or reaccreditation with the AO.
- Proposed § 424.57(c)(24) states that supplier locations must be resurveyed and reaccredited every year (rather than the current 3-year period).
- Proposed § 424.58(e)(8)(ii) states that CMS may, at any time, direct the

AO to perform a survey of an accredited supplier or group thereof.

- Proposed § 424.551 states that a DMEPOS supplier must enroll as a new supplier, receive a survey, and be reaccredited if it undergoes a non-exempted change in majority ownership.

There presently are approximately 46,500 accredited and enrolled DMEPOS suppliers, and about 1,780 accredited DMEPOS suppliers enroll in Medicare each year.

We currently permit a limited amount of sampling, which allows a DMEPOS AO to forgo performing a survey for certain supplier types, such as large chain suppliers in areas without high rates of fraud, waste, and abuse. While

we do not have exact figures regarding the number of supplier locations that are not surveyed due to sampling, we estimate—solely for purposes of this RIA—the amount to be roughly 50 percent of all chain suppliers.

(a) Initial Accreditation

The only additional initial accreditation burden associated with §§ 424.58(e)(8)(i)(A) would involve surveys of 50 percent of 1,780 of the aforementioned DMEPOS suppliers (or 890) at a cost to each supplier of \$2,000 per survey. Using our previous calculations, Table 75 outlines the annual hour and cost burdens.

TABLE 75: ADDITIONAL ANNUAL BURDEN OF INITIAL SURVEYS

BURDEN TO AO				
Task	Hour Burden Per Task	Total Hours	Wage (\$)	Total Cost (\$)
AO Burden — Survey	8	7,120 (8 x 890)	60.40	430,048
Survey Fee Collections	N/A	N/A	N/A	(1,780,000) (or \$2,000 cost x 890 surveys)
TOTAL	8	7,120	N/A	(1,349,952)
BURDEN TO SUPPLIER				
Burden to Supplier During Survey	6	5,340 (6 x 890)	44.28	236,455
Survey Fee	N/A	N/A	N/A	1,780,000
TOTAL	6	5,340	N/A	2,016,455
COMBINED NET BURDEN	14	12,460	N/A	666,503

(b) Reaccreditation

The additional burden associated with reaccreditation would involve 46,500 suppliers being surveyed and reaccredited twice more than they currently are within a 3-year period. This means that approximately 93,000 new re-surveys and reaccreditations would occur within the first 3 years of this rule, or 46,500 per year. Added to this would be the 3,560 new suppliers that would become initially accredited

and enrolled during this period (1,780 × 2 years), period, thus totaling an annual average of 48,280 (46,500 + 1,780) suppliers over this period. We will use the following baselines for our estimates:

- As previously noted, we project the time burden for a survey and reaccreditation to be 14 hours for the supplier and 20 hours for the AO.
- The fee will be \$3,000.
- The survey hour and wage estimates will remain the same (for

example, 8 hours per survey for the AO).

- The following wage rates will be used:
 - ++ Suppliers—\$44.28 (administrative personnel).
 - ++ AO application review—\$101.71 (same as the AO post-survey wage).
 - ++ AO surveyors—\$60.40.
- The supplier accreditation application process will take 8 hours (14 hours—6 hours for the survey), and the AO application review process will take

6 hours (20 hours—8 hours for the survey—6 hours for the final review/decision).

Table 76 accordingly outlines the burden associated with our annual resurvey and reaccreditation proposals:

TABLE 76: ESTIMATED ANNUAL NEW BURDEN OF RESURVEYS AND REACCREDITATIONS

BURDEN TO AO				
Task	Hour Burden Per Task	Total Hours	Wage (\$)	Total Cost (\$)
AO Burden – Application Review	6	289,680 (6 x 48,280)	101.71	29,463,353
AO Burden – Survey	8	386,240 (8 x 48,280)	60.40	23,328,896
AO Burden – Application/Post-Survey Review/Decision	6	289,680 (6 x 48,280)	101.71	29,463,353
Accreditation Fee Collections	N/A	N/A	N/A	(144,840,000) (or \$3,000 x 48,280)
TOTAL	20	965,600	N/A	(62,584,398)
BURDEN TO SUPPLIER				
Supplier Burden – Application Process	8	386,240 (8 x 48,280)	44.28	17,102,707
Burden to Supplier During Survey	6	289,680 (6 x 48,280)	44.28	12,827,030
Accreditation Fee	N/A	N/A	N/A	144,840,000
TOTAL	14	675,920	N/A	174,769,737
COMBINED NET BURDEN	N/A	1,641,520	N/A	112,185,339

(c) CMS-Directed Off-Cycle/Ad-Hoc Surveys

We project that CMS each year would direct the performance of 100 surveys outside of the proposed annual reaccreditation surveys and the

complaint surveys. We note that per proposed § 424.58(c)(1)(xxiii)(L), the AO must have a binding written agreement with its DMEPOS suppliers regarding whether the AO, the supplier in question, or both will assume the costs

of a CMS-directed survey. Solely for purposes of this impact analysis, we will project that the supplier would pay the survey cost. Table 77 outlines our estimated net costs of ad-hoc/CMS-directed surveys:

TABLE 77: ANNUAL BURDEN OF CMS-DIRECTED OFF-CYCLE/AD-HOC SURVEYS

BURDEN TO AO				
Task	Hour Burden Per Task	Total Hours	Wage (\$)	Total Cost (\$)
AO Burden – Survey	8	800 (8 x 100)	60.40	48,320
AO Burden - Post-Survey Review/Decision	6	600 (6 x 100)	101.71	61,026
Survey Fee Collections	N/A	N/A	N/A	(200,000) (or 100 x \$2,000)
TOTAL	N/A	1,400	Varies	(90,654)
BURDEN TO SUPPLIER				
Burden to Supplier During Survey	6	600 (6 x 100)	44.28	26,568
Survey Fee	N/A	N/A	N/A	200,000
TOTAL	N/A	600	N/A	226,568
COMBINED NET BURDEN	N/A	2,000	N/A	135,914

(d) Change in Majority Ownership

Our data indicates that, on average, approximately 3,768 DMEPOS suppliers

each year undergo an ownership change involving a new owner of 50.0 percent or more of the supplier. These surveys would be conducted outside the

reaccreditation, complaint, and CMS-directed survey processes. Table 78 outlines the following annual non-ICR burden estimates.

TABLE 78: ANNUAL BURDEN OF OWNERSHIP CHANGE SURVEYS

BURDEN TO AO				
Task	Hour Burden Per Task	Total Hours	Wage (\$)	Total Cost (\$)
AO Burden – Application Review	6	22,608 (6 x 3,768)	101.71	2,299,460
AO Burden - Survey	8	30,144 (8 x 3,768)	60.40	1,820,698
AO Burden – Application/Post-Survey Review/Decision	6	22,608 (6 x 3,768)	101.71	2,299,460
Accreditation Fee Collections	N/A	N/A	N/A	(18,840,000) (or \$5,000 fee x 3,768 surveys)
TOTAL	20	75,360	Varies	(12,420,382)
BURDEN TO SUPPLIER				
Burden to Supplier – Application Process	8	30,144 (8 x 3,768)	44.28	1,334,776
Burden to Supplier During Survey	6	22,608 (6 x 3,768)	44.28	1,001,082
Accreditation Fee	N/A	N/A	N/A	18,840,000
TOTAL	14	52,752	N/A	21,175,858
COMBINED NET BURDEN	N/A	128,112	N/A	8,755,476

(3) Additional Costs**(a) Conflicts of Interest**

We are proposing in new § 424.58(n) several prohibitions against AO conflicts of interest. For instance, proposed paragraph (n)(1) would state that if a DMEPOS AO's owner, surveyor, or employee has or had an interest in or relationship with a DMEPOS supplier the AO has accredited, the AO owner, surveyor, or other employee cannot participate in the survey of that supplier. We estimated in section VIII. of this proposed rule the AO's ICR burden of explaining in its initial and reapproval applications its policies/procedures for avoiding conflicts of interest. Beyond this, though, we are unable to establish a burden estimate for this proposal. The reason is that—aside from the recent criminal case cited in section VI.B. of this proposed rule—we do not know the extent to which conflicts of interest exist among our 8 DMEPOS AOs. We request feedback from stakeholders that could help us prepare such a projection.

(b) Consulting

We are proposing in new § 424.58(m) to prohibit consulting services—as that term would be defined in that paragraph (m)—by an AO and its associated consulting divisions or companies to any DMEPOS supplier to which the AO provides accreditation services: (1) prior to an initial accreditation survey; or (2) within 6 months of the next scheduled re-accreditation survey. We do not know the degree to which such services—which, for purposes of our proposal, focus mostly on simulated surveys—are furnished by DMEPOS AOs to DMEPOS suppliers. Therefore, we are soliciting comment from AOs and suppliers for purposes of establishing an estimate regarding the financial impact of this proposal.

(c) Additional Staff

We recognize that our proposal for annual DMEPOS supplier surveys and reaccreditations would require DMEPOS AOs to hire additional personnel. Regarding surveys, we mentioned earlier that AOs often have contracted staff perform them. Although we estimated the hour and cost burden associated with the additional surveys—using a \$60.40 wage and an 8-hour burden for each contracted surveyor—we have no means of calculating any precise increase in the AO's contract costs (such as additional payments to the contractor, costs of contract revisions, or securing a new contractor); this is because we are not privy to the terms of each AO's individual contract. Accordingly, we solicit comment from stakeholders regarding potential costs beyond those relating to the surveyor hour burden. As for AO personnel that review accreditation applications, make final decisions thereon, and perform other related tasks, we will project that the eight AOs combined will hire 12 nurses and 12 MHSMs to handle this additional work. In calculating the burden, we will utilize our previously noted \$90.00 and \$113.42 wages (for nurses and MHSMs, respectively), which results in a \$101.71 average wage. We will also assume a 2,080-hour work year. This results in an hour burden of 49,920 ((12 + 12) × 2,080) and a cost of \$5,077,363, which would include training costs. We welcome comments on this projection, particularly regarding the number of individuals AOs may have to hire.

(d) AO Ownership Changes

We are proposing in new § 424.58(o) to mirror the policies and procedures in 42 CFR 488.5(f) for situations where an AO undergoes a change of ownership. We are not including a burden estimate for this proposal because we do not

anticipate a DMEPOS AO undergoing an ownership change in the coming years,

(e) Rebates

We are proposing in new § 424.58(h) and (i) that if CMS terminates or suspends a DMEPOS AO's approved status, the AO must refund to a DMEPOS supplier all payments the supplier made to the organization:

- As part of the DMEPOS supplier's request for accreditation or reaccreditation; and
- Prior to the organization's notification to the DMEPOS supplier of its final decision regarding the supplier's request.

We estimated in the ICR section of this proposed rule that one AO would be terminated over the next 3 years and one AO suspended over this same period. We cannot project how many suppliers' applications (and surveys) would be in process at the time of termination or suspension. However, if we assume that 46,500 suppliers would be annually reaccredited and there are eight AOs, each AO on average would have 5,813 reaccreditations each year (46,500/8), or 484 (5,813/12) per month. If we further assume that an accreditation takes 4 months to complete, approximately 1,936 accreditations (484 × 4 months) could be in process with the AO at any given time. With a \$3,000 reaccreditation fee that would be refunded and 0.66 AOs being terminated or suspended each year ((one termination + one suspension)/3 years), this results in an annual total refund amount of \$3,833,280 (\$3,000 × 1,936 × 0.66).

(f) Form CMS-855S Initial Application—Required Fee

DMEPOS suppliers that are initially enrolling in Medicare due to a change in majority ownership under proposed § 424.551 would have to pay an application fee in accordance with

§ 424.514. The application fees for each of the past 3 calendar years were or are \$730 (CY 2025), \$709 (CY 2024), and \$688 (CY 2023). Consistent with § 424.514, the differing provider application fee amounts were predicated on changes/increases in the CPI for all urban consumers (all items; United States city average, CPI-U) for the 12-month period ending on June 30 of the previous year. While we cannot predict future changes to the CPI, the application fee amounts between 2023 and 2025 increased by an average of \$14 per year. We believe this is a reasonable barometer with which to establish estimates (strictly for purposes of this proposed rule) of the provider

enrollment application fee amounts in the first 3 calendar years of the final provision (that is, 2026, 2027, and 2028). Thus, we project a fee amount of \$744 in 2026, \$758 for 2027, and \$772 for 2028.

Applying these prospective fee amounts to the annual number of projected DMEPOS suppliers impacted by our change in majority ownership proposal—specifically, 3,300 suppliers—this results in a figure of \$2,455,200 (or $3,300 \times \$744$) in the first year, \$2,501,400 in the second year, and \$2,547,600 in the third year. Averaged over this 3-year period, the amount would be \$2,501,400, though there is ambiguity about whether this effect

would be classified as a transfer rather than a cost.(4) Total Costs

Table 79 outlines the total annual net costs of our changes to §§ 424.57 and 424.58. Two things must be mentioned regarding these figures. First, and as already noted, some costs could not be calculated due to a lack of available data. We reiterate our desire for stakeholders to furnish information to assist us in preparing impact assessments for these costs. Second, accreditation fees and refunds are not included in following table because they are considered transfers rather than costs. This is reflected in the accounting statement.

TABLE 79: TOTAL ANNUAL PROJECTED NET BURDEN OF CHANGES TO §§ 424.57 AND 424.58

Task	Total Hours	Net Financial Burden (\$)
Submission of Additional Data by AO or DMEPOS Supplier (ICR Burden)	18,636	1,227,319
Complaint Surveys	3,200	271,467
Additional Initial Accreditation Surveys	12,460	666,503
Annual Reaccreditations and Resurveys	1,641,520	112,185,339
CMS-Directed Surveys	2,000	136,004
Change in Majority Ownership Surveys	128,112	8,755,476
Additional Employees	49,920	5,077,363
TOTAL	1,855,808	128,319,471

As we wish to ensure that our estimates are as thorough as possible, we solicit comment on the following matters concerning our DMEPOS accreditation cost projections:

- Whether there are any other costs that we should consider in our analysis and, if so, what those costs are. This could include costs to parties other than DMEPOS suppliers and DMEPOS AOs.
- Whether our hour estimates for each noted task (for example, initial AO review of a reaccreditation application) are reasonable and, if not, what the revised estimate(s) should be.

(b) Savings

We previously stated in this proposed rule that we anticipate considerable savings to the Trust Funds and the taxpayers resulting from our DMEPOS AO provisions. This would stem from what we believe would be dramatic reductions in improper payments to DMEPOS suppliers due to non-compliance with the DMEPOS quality standards. More frequent surveys and reaccreditations would allow us to closely monitor suppliers for non-compliance. Indeed, we noted our concern that DMEPOS suppliers fall out

of compliance with the quality standards between their initial accreditation and their reaccreditation 3 years later.

Per our internal data, we project that an average of 339 DMEPOS suppliers are revoked each year based on a termination of their accreditation under § 424.57(c)(24). We noted in Table 72 that the average supplier of the 790 that were revoked for violation of a condition or standard in § 424.57(b) or (c) received \$488,328 over a 3-month period. Although we are unable to ascertain the number of these 790 suppliers that were revoked for violating § 424.57(c)(24), we believe it is appropriate to apply the \$488,328 figure to those revoked for a loss of accreditation.

Each supplier would be reaccredited three times more frequently than it presently is. Therefore, we will use a figure of 339 revocations occurring 2 years sooner than they otherwise would have and 339 occurring 1 year sooner than they otherwise would have. This results in a 3-year total of \$497 million ($= (2 \times 339 \times \$488,328) + (339 \times \$488,328)$), or a yearly average estimate of \$166 million ($= \$497 \text{ million} \div 3$). As

this is only a 3-month total, we must multiply it by 4 to achieve an annual savings ($3 \text{ months} \times 4 = 12 \text{ months}$), which we project to be \$664 million. (It should be noted that there would be double-counting if the estimate resulting from this calculation were added to the \$386 million estimate in Table 72—because for the overlap that exists between the estimated 790 and 1,017 suppliers, either the retroactive collection brings in reimbursements equal to three months' worth of improper payments, leaving only 9 months' worth to be affected by the reaccreditation, or reaccreditation brings in 12 months' worth, leaving none to be affected by retroactive collection.)

7. DMEPOS Prior Authorization

We propose to add technical language to § 414.234 (c)(1) that provides for the exemption process in § 414.234 (c)(1)(ii). We also propose to exempt a supplier from the mandatory prior authorization process (OMB Control No. 0938–1293) in newly proposed § 414.234 (c)(1)(ii)(A) upon demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption

would remain in effect until CMS withdraws the exemption. In proposed § 414.234 (c)(1)(ii)(B), we would provide 60-day notice of an exemption from mandatory prior authorization requirements. Similarly, we propose to provide 60-day notice if an exemption is withdrawn. We would exempt suppliers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a periodic assessment. If the rate of prior authorizations with non-affirmations submitted becomes higher than 10 percent during an annual assessment, we will consider withdrawing exemption for the specific noncompliant supplier, until the following periodic assessment.

a. MAC Workload Reduction

Based upon our internal data for CY 2024, looking across the 4 Durable Medical Equipment Medicare Administrative Contractor (DME MAC) jurisdictions, we assessed the number of suppliers that would have met the 90 percent threshold needed to qualify for an exemption from mandatory prior authorization each year. Based upon contractual costs to complete mandatory prior authorization, the total cost for all 4 DME MACs' workload was \$13,194,555. We assessed the reduction in workload, accounting for compliant suppliers that met the 90 percent threshold, to be an average of 17 percent reduction, or \$2,243,074 in savings in 1

year had this process been in place for CY 2024. We note that the number of compliant suppliers (for example: 6 percent in 2024) does not directly reflect the number of PARs submitted or the workload required by the MACs. In our assessment, we found that suppliers submit PARs for multiple items and multiple beneficiaries, and the most compliant suppliers submit more PARs than the noncompliant suppliers.

b. Supplier Burden Reduction

A detailed analysis of the supplier burden reduction is found in the ICR section of this rule; however, an overview of the totals is found herein.

TABLE 80: TOTAL ANNUAL BURDEN

Year One	Year Two	Average Annual Burden
\$5,988,332	\$6,727,543	\$6,357,938

We are unable to determine the number of compliant suppliers in future

years. However, if we average the data from previous years, the average

percentage of compliant suppliers or PTANs is 4 percent.

TABLE 81: AVERAGE EXEMPT SUPPLIERS BY YEAR

CY	Total PTAN	PTAN Who Meet Criteria	Percentage of Exempt PTAN
2022	7,049	148	2%
2023	8,048	249	3%
2024	9,298	543	6%

The total burden is assessed in Table 80. By reducing the total average annual burden (\$6,357,938) by the average number of suppliers (represented by PTANs) *not* submitting prior authorization requests by 4 percent, we have an average savings of \$254,318 per year.

c. Total Burden Reduction

We estimate the reduction of burden for suppliers to be \$254,318 per year. We estimate the reduction in workload for the MACs to be \$2,243,074 per year. Combined, we estimate these savings to equal a total sum of \$2,497,392 per year.

8. DMEPOS Competitive Bidding Program

We believe that the provisions of this proposed regulation related to the DMEPOS CBP and payment for CGMs have no net impact. The DMEPOS CBP is required to be implemented by the Act and impacts associated with its

implementation have already been accounted for.

a. Changes to the Calculation of SPAs and Number of Contracts To Be Awarded

From 2011 to 2018, the competitive bidding program calculated SPAs based on the median (50th percentile) of winning bids but targeted a large number of contracts to award. Current regulations set the SPA as the maximum (100th percentile) of the winning bids, but did not generate the savings required to award contracts under the Act. We expect that the combination of setting the SPA as the 75th percentile and reducing the number of contracts to be awarded will result in SPAs broadly similar to those seen in previous, successful rounds of competitive bidding, and therefore result in zero net expenditure.

b. Application of Annual Inflation Update Factors to SPA

In previous rounds of competitive bidding, bidders were expected to account for expected inflation over the contract period when making their bids and thus bid higher to account for these costs. With this change, we expect that bidders will bid lower prices, based on current year costs, with the understanding that these will be escalated by inflation in future years. Over the course of the contract, there should be no net impact from this change.

c. Revision of Payment for CGMs

The change in payment category for CGMs will have no net impact because the Medicare payment amount calculated as the bundled rental payment under the classification as items that require frequent and substantial servicing will equal the expected payments that Medicare would

have made under the current payment category.

d. Other Provisions

The other provisions of this rule are purely an administrative effort with no impact on Medicare coverage or expenditure, and, for this reason, has no cost or transfer associated with it.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach used in estimating the number of entities reviewing this proposed rule.

We recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule. Therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. Finally, in our estimates, we have used the 973 number of timely pieces of correspondence on the CY 2025 HH PPS proposed rule as our estimate for the number of reviewers of this rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. We seek comments on this assumption. Using the median hourly wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed rule is \$106.42 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it would take approximately 2.77 hours for the staff to review half of this proposed rule. For each entity that

reviews this proposed rule, the estimated cost is \$294.78 (2.77 hours × \$106.42). Therefore, we estimate that the total cost of reviewing this proposed rule is \$286,820 (\$294.78 × 973 reviewers).

E. Alternatives Considered

1. HH PPS

We described in section II.C.1.e. of this proposed rule, to achieve budget neutrality as required by law, we calculated a permanent adjustment by determining what the 30-day base payment amount should have been in CYs 2020, 2021, 2022, 2023, and 2024 in order to achieve the same estimated aggregate expenditures as obtained from the simulated 60-day episodes. One alternative to the proposed 4.059 percent permanent adjustment included proposing half the calculated permanent adjustment similar to how we finalized the permanent adjustment for CY 2025. Another alternative would be to propose a phase-in approach, where we could reduce the permanent adjustment, by spreading out the CY 2026 permanent adjustment over a specified period of years, rather than halving the adjustment in CY 2026. Another alternative would be to not propose an adjustment and delay the implementation of the permanent adjustment to a future year. However, we believe that a reduction, a phase-in approach, or delay in the permanent adjustment would not be appropriate, as reducing, phasing in, or delaying the permanent adjustment would further impact budget neutrality and likely lead to a compounding effect creating the need for a larger reduction to the payment rate in future years.

Finally, we proposed to implement a temporary adjustment to begin reconciling retrospective overpayments from CYs 2020, 2021, 2022, 2023, and 2024, as discussed in section II.C.1.f. of this proposed rule. Section 1895(b)(3)(D)(iii) of the Act gives CMS the authority to make a temporary adjustment in a time and manner appropriate though notice and comment rulemaking.

We considered not applying a temporary adjustment, as in prior proposed rules. Another alternative would be to apply a temporary adjustment factor to the CY 2026 payment rate that would recoup the calculated temporary adjustment dollar amount, to date, of \$5.3 billion. However, due to the growing temporary adjustment amount calculated from CYs 2020 through 2024, to delay the implementation of a temporary adjustment would lead to many more

years of reductions to the payment rate to reach budget neutrality. Also, as stated previously in this proposed rule, we believe that applying both the permanent adjustment of –4.059 percent and a temporary adjustment accounting for the temporary adjustment dollar amount of \$5.3 billion to the CY 2026 payment rate may adversely affect HHAs given the magnitude of the combined adjustments to the payment rate in a single year. Although we are not establishing a timeframe to recoup the calculated temporary adjustment dollar amount of \$5.3 billion, we believe it is prudent to begin implementing some of the adjustment in order to begin to slow its continued growth. Postponing the collection of this large dollar amount would lead to an extended duration of temporary adjustments or larger reductions to the payment rates in future years to reach budget neutrality sooner.

Therefore, we believe it is best to propose the implementation of the permanent adjustment decrease of 4.059 percent and a temporary adjustment decrease of 5 percent to the CY 2026 base payment rate.

2. HH QRP

Regarding our proposal to remove the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure, we considered keeping the measure, but determined the cost and burden associated with maintaining these measures outweigh the benefit of their continued collection and are proposing to remove them.

Regarding our proposal to remove four standardized patient assessment data elements we are removing these in an effort to reduce burden. We considered keeping these but believe that removing would help reduce burden.

Finally, regarding proposals to amend the reconsideration request policy and process, we considered the alternative of leaving the policy language unchanged. However, we have noted some areas in our policy where HHAs may benefit from clearly demarcated deadlines regarding requests for reconsideration.

3. Provider Enrollment

There were two principal alternatives we considered. First, we contemplated proposing more than the nine retroactive revocation grounds addressed in § 424.535(a)(8) and (g)(2)(viii) through (xiv). However, we decided to only include these nine and to address potential other grounds via future rulemaking. Second, we

considered a 6-month period (instead of our proposed 12-month timeframe) for our proposal in new § 424.547 regarding ordering, certifying, and referring physicians and non-physician practitioners. Given that this would be a new provision and that a 12-month timeframe would be consistent with that which had applied to non-billing providers and suppliers for many years, we decided that a 12-month period would be most appropriate.

4. DMEPOS Supplier Accreditation Organizations

There are several alternatives we contemplated in preparing our proposed revisions to §§ 424.57 and 424.58.

First, we considered retaining the current 3-year cycle for resurveys and reaccreditations. However, as explained in section VI. of this proposed rule, we are concerned that unqualified suppliers are becoming accredited and that existing accredited suppliers are falling out of compliance with the quality standards between their 3-year reaccreditation periods. This has potentially resulted in many millions of dollars being improperly paid to non-adherent suppliers. Only through closer vetting of suppliers via more frequent surveys can we be better assured that Medicare is only paying legitimate suppliers.

Second, existing § 424.58(b)(1) lists detailed information that DMEPOS AOs must submit with their initial approval and reapproval applications. We considered retaining this list as is and even eliminating several items therefrom so as to ease the application burden on AOs. However, as we noted in section VI.B. of this proposed rule, we have not re-approved any existing AOs since 2006. Considering this long passage of time, we believe it is critical to have as much data as possible about our AOs if and when an AO re-approval process commences after the effective date of our DMEPOS AO provisions, if finalized. Therefore, we proposed to increase the scope of information that AOs must submit with their applications. This would help ensure that: (i) we have all the data needed to make informed application decisions; and (ii) only qualified organizations perform DMEPOS accreditation activities.

Third, we contemplated duplicating the requirements that initial AO application submissions, initial AO application decisions, and AO terminations be published in the **Federal Register**. We ultimately

declined this approach and instead proposed to make these pronouncements—including those for suspensions—on our CMS website. We believe this would facilitate faster communication with interested stakeholders.

Fourth, and in a broader context, we considered the extent to which our proposed provisions should parallel those in part 488. We contemplated having practically all of provisions be distinct from part 488, meaning there would be little duplication. This was primarily because of the excessive program integrity risk that DMEPOS suppliers have traditionally posed to Medicare and the consequent need to tailor our provisions to effectively address it. While we indeed proposed a significant number of provisions that are either modifications of those in part 488 or are not included in part 488 at all, we decided to mirror part 488 to the extent possible. As explained in section VI.B. of this proposed rule, we believed this would create precedent for some of our provisions and take advantage of existing, well-established procedures regarding certified provider and supplier accreditation.

5. Prior Authorization of Certain DMEPOS Items

Regarding our proposal to clarify circumstances under which CMS would exempt a supplier from the prior authorization process in newly proposed § 414.234(c)(1)(ii)(A) upon demonstration of compliance with Medicare coverage, coding, and payment rules, we did not consider the alternative of not providing prior authorization exemptions to certain suppliers, as we believe the benefits of the exemption program provides savings to both the Trust Funds, as well as eligible suppliers.

We did not consider alternatives to the 90 percent provisional affirmation threshold. We believe that by achieving this percentage, the supplier would be demonstrating an understanding of the requirements for submitting accurate claims. We do not believe it is necessary for a supplier to achieve 100 percent compliance to qualify for an exemption because unintentional and sporadic errors could occur that are not deliberate or systemic attempts to submit claims that are not payable. We use a 90 percent threshold for exempting hospital OPD providers from the prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding, and

payment rules. Additionally, we use a 90 percent affirmation rate threshold in our Review Choice Demonstration for Home Health Services for home health agencies demonstrating compliance with Medicare requirements. In that program, home health agencies select from different initial review choices, such as pre-claim review (which is similar to prior authorization) and postpayment review of all home health billing periods. After a 6-month review period, agencies are evaluated to determine their review approval rate. If the agency meets the 90 percent threshold, they have additional review options open to them, including relief from most reviews. This threshold represents the best balance between the need to review PARs, while reducing burden on suppliers and effectively utilizing contractor resources, creating savings to the Trust Funds.

6. DMEPOS Competitive Bidding Program

Alternative possibilities for setting the SPA were considered. However, the current method of using the maximum bid did not result in savings while the previous method of using the median, definitionally, forced half the suppliers to accept a SPA below their bid. We believe the 75th percentile represented the best balance of the need to reduce the impact of outlier bids while paying most suppliers at or above their bid amount.

Similarly, while we considered other methods to determine the number of contracts to offer in each CBA, we concluded that the chosen methodology results in the best method of balancing the need to ensure a sufficient number of bidders to meet the anticipated needs of beneficiaries, while ensuring an adequate level of business for winning bidders.

We did not consider alternatives to the other proposed changes as we believe these specific changes were needed to ensure the efficient operation of the CBP.

F. Accounting Statements and Tables

1. HH PPS

Consistent with OMB Circular A-4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table GG-82, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2026 HH PPS provisions of this proposed rule.

TABLE 82: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2025 TO CY 2026

Category	Transfers
Annualized Monetized Transfers	-\$1.135 billion
Bearers of Transfer Loss	Medicare HHAs

2. HH QRP

Consistent with OMB Circular A–4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 83, we have prepared an accounting statement showing the classification of

the costs associated with the ICRs for the proposed HH QRP provisions in CY 2026.

the costs associated with the ICRs for the proposed HH QRP provisions in CY 2026.

TABLE 83: HH QRP ESTIMATED COSTS FROM CY 2025 TO CY 2027

Category	Benefit
The total economic impact of these proposals including the removal of one patient COVID-19 vaccine item and proposals for the removal of one Living Situation item, two Food items, and one Utilities item proposed for implementation in CY 2026.	\$ -17,810,282

3. Expanded HHVBP Model

Consistent with OMB Circular A–4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 84, we have prepared an accounting statement showing the classification of

the transfers and benefits associated with the CY 2026 HHVBP provisions of this proposed rule.

the transfers and benefits associated with the CY 2026 HHVBP provisions of this proposed rule.

TABLE 84: ACCOUNTING STATEMENT: EXPANDED HHVBP MODEL CLASSIFICATION OF ESTIMATED TRANSFERS FOR CYs 2023 – 2027

Category	Transfers	Discount Rate	Period Covered
Annualized Monetized Transfers	-\$662.4 Million	7%	CYs 2023-2027
Annualized Monetized Transfers	-\$669.7 Million	3%	CYs 2023-2027
Bearers of Transfer Loss	Hospitals and SNFs		

4. Provider Enrollment

Consistent with OMB Circular A–4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 85, we have prepared an accounting statement showing the classification of

the benefits associated with the CY 2026 provider enrollment provisions of this proposed rule. The figure below

includes the combined total from our retroactive revocation proposals (\$2.197 billion) and our change in majority ownership provisions (\$2.5 million in Form CMS–855S application fees).

TABLE 85: ACCOUNTING STATEMENT: PROVIDER ENROLLMENT - CY 2026

Category	Monetary Amount (Millions \$)
Transfers to the Federal Government	2,200

5. DMEPOS Supplier Accreditation Organizations

Consistent with OMB Circular A–4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 86, we have prepared an accounting statement showing the classification of the costs, transfers and benefits associated with the CY 2026 DMEPOS accreditation provisions of this

proposed rule. For the costs, the DMEPOS AO figure of \$95.2 million is the total cost to the AOs out of the \$128.3 million reflected in Table 79. That is, we combined all of the net AO cost burdens from the tables and explanations in sections VIII. (ICR costs for AOs) and IX.C.6.a. of this proposed rule to arrive at the \$95.2 million figure. As noted in the “Burden to AO” portions of the tables, these costs mostly

arose from reaccreditation application reviews, surveys, and post-survey reviews and decision. The supplier costs, meanwhile, reflect the remainder of the the \$128.3 million total in the accounting statement. As with the AO costs, the supplier costs (excluding accreditation fee payments and Form CMS–855S application fees, which are transfers) stem mostly from surveys and the reaccreditation application process.

TABLE 86: ACCOUNTING STATEMENT: DMEPOS ACCREDITATION ANNUAL COSTS AND TRANSFERS

Category	Monetary Amount (Millions \$)
Costs	
DMEPOS AOs	95.2
DMEPOS Suppliers	33.1
Transfers	
Accreditation/Survey Fees	165.8
Bearers of Transfer Gain	DMEPOS AOs
Refunds	3.8
Bearers of Transfer Gain	DMEPOS Suppliers
To Federal Government	664

6. Proposed Exemption Process for Prior Authorization of Certain DMEPOS Items

As required by OMB Circular A–4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 87, we have prepared an accounting statement showing the classification of

the costs, transfers and benefits associated with the Exemption Process for Prior Authorization of Certain DMEPOS Items of this proposed rule.

TABLE 87: ACCOUNTING STATEMENT: EXEMPTION PROCESS FOR PRIOR AUTHORIZATION OF CERTAIN DMEPOS ITEMS ANNUAL COSTS AND BENEFITS

Category	Monetary Amount (Millions \$)
Benefits	
To Federal Government	2.2
To DMEPOS Suppliers	0.3

7. Overall Accounting Statement

As required by OMB Circular A–4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 88, we have prepared an accounting statement showing the classification of

the transfers, costs/savings, and benefits for certain provisions of this proposed rule for CY 2026.

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TABLE 88: ACCOUNTING STATEMENT - CLASSIFICATIONS OF ESTIMATED TRANSFERS, COSTS, AND BENEFITS FOR CY 2026 (in MILLIONS)

Category	Amount (\$ in millions)
TRANSFERS	
HH-Related Provisions	
HHS PPS--Annualized monetized transfers	-1135
HHVBP	-662.4 to -669.7
DMEPOS-Related Provisions	
DMEPOS AOs	165.8
From DMEPOS suppliers to DMEPOS AOs in accreditation/survey fees	
DMEPOS Suppliers	3.8
From DMEPOS AOs to DMEPOS suppliers in refunds.	
Other Provisions	
Provider Enrollment	2,200
From providers to the Federal government	
COSTS/SAVINGS	
DMEPOS-Related Provisions	
DMEPOS AOs	95.2
DMEPOS Suppliers	33.1
BENEFITS	
HH-Related Provisions	
HH QRP	-17.8
DMEPOS-Related Provisions	
DMEPOS Prior Authorization	2.5

BILLING CODE 4120-01-C*G. 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, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. In addition,

HHAs are small entities, as that is the term used in the RFA. Individuals and States are not included in the definition of a small entity.

The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the U.S. business economy. We utilized the NAICS U.S. industry title “Home Health Care

Services” and corresponding NAICS code 621610 in determining impacts for small entities. The NAICS code 621610 has a size standard of 19 million¹⁰³ and approximately 96 percent of HHAs are considered small entities. Table 89 shows the number of firms, revenue, and average revenue per firm for the home health care services category (NAICS 621610).

¹⁰³ https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023.xlsx.

TABLE 89: NUMBER OF FIRMS, REVENUE, AND AVERAGE REVENUE PER FIRM OF HOME HEALTH CARE SERVICES FOR NAICS CODE 621610

NAICS	NAICS Description	Enterprise Size (\$1,000)	Number of Firms	Receipts (\$1,000)	Average Receipts Per Firm (\$1,000)
621610	Home Health Care Services	<100	6,361	232,967	\$36.62
621610	Home Health Care Services	100-499	7,099	1,869,713	\$263.38
621610	Home Health Care Services	500-999	3,866	2,829,374	\$731.86
621610	Home Health Care Services	1,000-2,499	5,218	8,370,496	\$1,604.16
621610	Home Health Care Services	2,500-4,999	2,560	8,833,076	\$3,450.42
621610	Home Health Care Services	5,000-7,499	885	5,275,636	\$5,961.17
621610	Home Health Care Services	7,500-9,999	450	3,789,016	\$8,420.04
621610	Home Health Care Services	10,000-14,999	466	5,256,982	\$11,281.08
621610	Home Health Care Services	15,000-19,999	235	3,621,448	\$15,410.42
621610	Home Health Care Services	>20,000	1,058	73,271,709	\$69,254.92
621610	Home Health Care Services	Total	28,198	113,350,417	\$4,019.80

Source: Data obtained from United States Census Bureau table “us_6digitnaics_rcptsize_2022” (SOURCE: 2022 SUSB Annual Data Tables by Establishment Industry) Release Date: 4/10/2025: https://www2.census.gov/programs-surveys/susb/tables/2022/us_6digitnaics_rcptsize_2022.xlsx

Notes: The ‘Average Receipts Per Firm’ column is calculated as the Receipts (\$1,000)/Number of firms. The ‘Total’ row represents all the home health care services firms under NAICS 621610. Overall receipts (revenue) for the 28,198 firms (NAICS 621610) are approximately \$113 billion.

The economic impact assessment is based on estimated Medicare payments (revenues) and HHS’s practice in interpreting the RFA is to consider effects economically “significant” only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs’ visits are Medicare paid visits and therefore the majority of HHAs’ revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS proposed rule will have a significant economic impact on a substantial number of small entities.

Specifically, we estimate that the net impact of the payment policies in this proposed rule will be a negative 6.4 percent impact in the aggregate for CY 2026 or approximately – \$1.135 billion. Table 67 details the total percentage payment reduction by number of 30-day periods. We estimate that smaller HHAs (those with less than 100 periods of care and thereby lower overall revenues) will receive a negative 6.8 percent payment impact in CY 2026. Also, we estimate that larger HHAs (those with more than 1,000 periods of care and thereby higher overall revenues) will receive a negative 6.2 percent payment impact in CY 2026. Furthermore, table 67 details the total percentage payment impact by facility

location. We estimate that HHAs located in the Pacific region will receive the largest impact reflecting a negative 7.5 percent payment impact. As discussed in the preamble, the net decrease in CY 2026 is mostly driven by the impact of the permanent and temporary adjustments which are reflected in the third and eighth columns of table 67. We solicit comments on this RFA analysis on small entities.

Regarding options for regulatory relief, we note that section 1895(b)(3)(D)(i) of the Act requires CMS to annually determine the impact of differences between the assumed behavior changes finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56455) and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Additionally, section 1895(b)(3)(D)(ii) and (iii) of the Act requires us to make permanent and temporary adjustments to the payment rate to offset for such increases or decreases in estimated aggregate expenditures through notice and comment rulemaking. While we find that the – 4.059 percent permanent adjustment, described in section II.C.1.g. of this proposed rule, is necessary to offset the increase in estimated aggregate expenditures for CYs 2020 through 2024 based on the impact of the differences between assumed behavior changes and actual behavior changes, we will also continue to reprice claims,

per the finalized methodology, and make any additional adjustments at a time and manner deemed appropriate in future rulemaking.

As discussed previously in the Alternatives Considered section of this proposed rule, we explored alternatives to the proposed – 4.059 percent permanent adjustment including a phase-in approach, where we could reduce the permanent adjustment, by spreading out the CY 2026 permanent adjustment over a period of years. Another alternative would be to delay the permanent adjustment to a future year. However, we believe that a reduction to the permanent adjustment, a phase-in approach, or delay in the permanent adjustment would not be appropriate, as reducing, phasing in, or delaying the permanent adjustment would further impact budget neutrality and likely lead to a compounding effect creating the need for a larger reduction to the payment rate in future years. In addition, we explored alternatives to the proposed – 5 percent temporary adjustment to reconcile retrospective overpayments in CYs 2020 through 2024. However, as stated previously in this proposed rule, we believe that applying both the permanent adjustment of – 4.059 percent and a temporary adjustment accounting for the temporary adjustment dollar amount of \$5.3 billion to the CY 2026 payment rate may adversely affect HHAs given the magnitude of the combined adjustments to the payment rate in a

single year. Although we are not establishing a time frame to recoup the calculated temporary adjustment dollar amount of \$5.3 billion, we believe it is prudent to begin implementing some of the adjustment in order to begin to slow its continued growth. Postponing the collection of this large dollar amount would lead to an extended duration of temporary adjustments or larger reductions to the payment rates in future years to reach budget neutrality sooner. We solicit comments on the overall HH PPS RFA analysis.

Among the over 7,000 HHAs that are estimated to qualify to compete in the expanded HHVBP Model, we estimate that the percent payment adjustment resulting from this proposed rule would be larger than ± 3 percent, in magnitude, for about 660 competing HHAs (9

percent) (estimated by applying the 5 percent maximum payment adjustment under the expanded Model to CY 2023 data). As a result, more than the RFA threshold of 5 percent of HHAs nationally would be significantly impacted.

In addition, section 1102(b) of the Act requires us to prepare an RIA 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 RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule is not applicable to hospitals. Therefore, the Secretary has certified that this proposed rule would

not have a significant economic impact on the operations of small rural hospitals.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$8.0 million to \$41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. This proposed rule primarily affects pharmacies and drug stores and home health equipment rental suppliers.

TABLE 90: DMEPOS SUPPLIERS SIZE STANDARDS

NAICS (6-digit)	Industry Subsector Description	SBA Size Standard/Small Entity Threshold	Total Small Businesses
446110	Pharmacies and Drug Stores	\$37.5 million	18,952
532283	Home Health Equipment Rental	\$41 million	553

Source: SUSB 2017 Country Business Patterns and Economic Census

Since we are uncertain of the DMEPOS suppliers' composition, we are asking the public for aid in

understanding the various industries that supply DMEPOS products. So far,

we have identified only the two industries in table 91.

TABLE 91: DMEPOS SUPPLIERS' CONCENTRATION RATIOS (PHARMACIES AND DRUG STORES AND HOME HEALTH EQUIPMENT RENTAL)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Total Average Revenue
SMALL FIRMS	19,505	100.0%	\$3,374,384
<100,000	706	3.6%	\$51,647
100,000-499,999	2,139	11.0%	\$290,675
500,000-999,999	2,065	10.6%	\$744,226
1,000,000-2,499,999	5,693	29.2%	\$1,745,060
2,500,000-4,999,999	5,255	26.9%	\$3,559,904
5,000,000-7,499,999	1,839	9.4%	\$6,032,844
7,500,000-9,999,999	709	3.6%	\$8,506,154
10,000,000-14,999,999	573	2.9%	\$11,926,209
15,000,000-19,999,999	226	1.2%	\$16,037,279
20,000,000-24,999,999	103	0.5%	\$18,479,010
25,000,000-29,999,999	65	0.3%	\$25,465,123
30,000,000-34,999,999	49	0.3%	\$27,426,041
35,000,000-39,999,999	37	0.2%	\$28,005,054
40,000,000-49,999,999	46	0.2%	\$31,703,478
LARGE FIRMS			
Receipts ≥50 million	318	NA	\$690,720,449.69

SOURCE: 2017 County Business Patterns and Economic Census.

Note: Home Health Equipment Rental includes firms earning up to \$49.9 million, which is greater than the \$41 million SBA size standard, and Pharmacies and Drug Stores include firms earning up to \$39.9 million, which is greater than the \$37.5 million SBA size standard.

As can be seen in table 91, almost all DMEPOS suppliers are small entities as that term is used in the RFA.¹⁰⁴ Additionally, table 91 shows the disproportionate impacts among firms, and between small and large firms. In table 91, both industries, Pharmacies and Drug Stores and Home Health Equipment Rental firm size (by receipts), firm count, percentage of small firms, and total average revenue were aggregated to determine the DMEPOS concentration ratios.

For purposes of the RFA, approximately 98.4 percent of pharmacies and drugs stores and home health equipment rental industries are considered small businesses according to the SBA's size standards with total revenues of \$49.9 million or less in any 1 year. Individuals and states are not included in the definition of a small entity.

This rule does not affect health care enterprises operated by small government entities such as counties or towns with populations 50,000 or less. HHS generally uses a revenue impact of 3 to 5 percent as a significance

threshold under the RFA. The RFA threshold analysis, therefore, indicates that there is not a significant economic impact on a substantial number of small entities. Furthermore, the regulation review costs mentioned previously, is de minimis and will not impose any additional burden on these small businesses. Therefore, the Secretary certifies that this final 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 an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a

proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA 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 2025, that threshold is approximately \$187 million. This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than \$187 million in any one year.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local

¹⁰⁴ Note, the entire population of DMEPOS suppliers is not known at this time. However, based on our experience, the majority of DMEPOS suppliers are covered in the two industries identified.

governments, preempts State law, or otherwise has federalism implications. We have reviewed this proposed rule under these criteria of Executive Order 13132 and have determined that it would not impose substantial direct costs on State or local governments.

J. Unleashing Prosperity Through Deregulation

Executive Order 14192, titled “Unleashing Prosperity Through Deregulation” was issued on January 31, 2025, and requires that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations”

K. Conclusion

In conclusion, we estimate that the provisions in this proposed rule will result in an estimated net decrease in home health payments of 6.4 percent for CY 2026 (–\$1.135 billion). The \$1.135 billion decrease in estimated payments for CY 2026 reflects the effects of the proposed CY 2026 home health payment update percentage increase of 2.4 percent (\$425 million increase), an estimated 3.7 percent decrease in payments that reflects the effects of the permanent adjustment (\$655 million decrease) an estimated 4.6 percent decrease that reflects the effects of the temporary adjustment (\$815 million decrease) and an estimated 0.5 percent decrease that reflects the effects of an updated FDL (\$90 million decrease). Lastly, the implementation of the HH QRP proposed policy is estimated to increase the costs to HHAs by \$1,058.88 per HHA annually, or \$12,604,894.62 in the aggregate for HHAs annually.

X. 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.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 24, 2025.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices,

Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.800 is amended by revising paragraph (b)(2) to read as follows:

§ 405.800 Appeals of CMS or a CMS contractor.

* * * * *

(b) * * *

(2) The effective date of a revocation is as specified in § 424.535.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 3. The authority for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 4. Section 414.234 is amended by revising paragraph (c)(1) introductory text and adding paragraphs (c)(1)(ii)(A) and (B) to read as follows:

§ 414.234 Prior authorization for items frequently subject to unnecessary utilization.

* * * * *

(c) * * *

(1) *Items requiring prior authorization.* CMS publishes in the **Federal Register** and posts on the CMS Prior Authorization website a list of items, the Required Prior Authorization List, that require prior authorization as a condition of payment, unless otherwise exempt under paragraph (c)(1)(ii) of this section.

* * * * *

(ii) * * *

(A) An exemption is provided for a supplier that achieves a rate of payable claims submitted, based on Medicare's billing, coding or payment requirements, of at least 90 percent during an initial or periodic review and remains in effect until CMS withdraws the exemption. An exemption of a supplier is withdrawn if the rate of non-payable claims submitted, based on Medicare's billing, coding or payment requirements, becomes higher than 10 percent, based upon a periodic assessment.

(B) CMS provides a notice of an exemption or withdrawal of an exemption to the supplier at least 60 days before the effective date.

■ 5. Section 414.402 is amended by—
■ a. Adding the definitions of “Adjusted fee schedule amount” and “Competition”;
■ b. In the definition of “Competitive bidding program” removing the phrase “Competitive bidding program” and adding in its place “Competitive bidding program (CBP)”;
■ c. Adding paragraph (6) to the definition of “Item”; and
■ d. Adding the definitions of “Remote item delivery competitive bidding program”, “Remote item delivery item”, and “Unadjusted fee schedule amount”.

The additions read as follows:

§ 414.402 Definitions.

* * * * *

Adjusted fee schedule amount means the payment amount established for the item under one of the following:

(1) Subpart C of this part, with the application of § 414.105.

(2) Subpart D of this part, with the application of § 414.210(g).

(3) Subpart Q of this part, with the application of § 414.1690.

* * * * *

Competition means a competitive bidding area and product category combination for which a bidding entity submits a bid and for which a contract supplier enters into a DMEPOS CBP supplier contract to furnish items and

services within the product category to beneficiaries residing within the competitive bidding area.

* * * *

Item * * *

(6) Other medical equipment described in section 1861(m)(5) of the Act, including ostomy, tracheostomy, and urological supplies.

* * * *

Remote item delivery competitive bidding program means a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under the product category to all Medicare beneficiaries regardless of where they live in the CBA. The CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country.

Remote item delivery item means an item falling under a remote item delivery competitive bidding program that may be shipped or delivered to a beneficiary's home, regardless of the method of delivery or picked up at a local pharmacy or supplier storefront if the beneficiary or caregiver for the beneficiary chooses to pick the item up in person.

* * * *

Unadjusted fee schedule amount means the payment amount established for the item under one of the following:

(1) Subpart C of this part, without the application of § 414.105.

(2) Subpart D of this part, without the application of § 414.210(g).

(3) Subpart Q of this part, without the application of § 414.1690.

* * * *

■ 6. Section 414.408 is amended by—

■ a. Revising paragraph (b); and

■ b. Adding paragraphs (e)(2)(v) and (g)(6), and (m).

The revision and additions read as follows:

§ 414.408 Payment rules.

* * * *

(b) *Changes to the single payment amount.* (1) For the second year (12-month period) of a DMEPOS CBP supplier contract period, the single payment amount for each item under each competitive bidding program is updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) for the 12-month period ending 6 months prior to the start of the second year of the applicable DMEPOS CBP supplier's contract period.

(2) For the third year (12-month period) of a DMEPOS CBP supplier contract period, if applicable, the single

payment amounts are updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) for the 12-month period ending 6 months prior to the start of the third year of the applicable DMEPOS CBP supplier contract period.

(3) In no case can the updated single payment amount for an item in the applicable CBA be greater than the unadjusted fee schedule amount for the item in such area or 110 percent of the adjusted fee schedule amount for the item in such area.

* * * *

(e) * * *

(2) * * *

(v) A Medicare enrolled provider or supplier, as the terms are defined under 42 CFR 400.202, that is operated by the Indian Health Service (IHS) or a Tribe or Tribal organization in accordance with the Indian Self Determination and Education Assistance Act (25 U.S.C. 5301 et seq).

(g) * * *

(6) Other medical equipment described in section 1861(m)(5) of the Act, including ostomy, tracheostomy, and urological supplies.

* * * *

(m) *Special temporary transition rules for payment for supplies and accessories necessary for the effective use of beneficiary owned continuous glucose monitors and insulin infusion pumps.* CMS continues, as applicable, to make separate payments under the DMEPOS competitive bidding program for supplies and accessories for class II continuous glucose monitors or insulin infusion pumps owned by the beneficiary at the time a competitive bidding program is phased in for class II continuous glucose monitors or insulin infusion pumps for the first time in a CBA where the beneficiary resides until coverage for the beneficiary-owned equipment ends, the equipment is no longer used, or at any point when the equipment has been replaced with rented equipment under the DMEPOS CBP.

■ 7. Section 414.412 is amended by—

■ a. Revising paragraph (b)(2);

■ b. Redesignating paragraphs (b)(3) through (5) as paragraphs (b)(6) through (8);

■ c. Adding new paragraphs (b)(3), (4) and (5);

■ d. Adding paragraphs (b)(9) through (12);

■ e. Revising paragraph (g)(3); and

■ f. Adding paragraph (g)(5).

The revisions and additions read as follows:

§ 414.412 Submission of bids under a competitive bidding program.

* * * *

(b) * * *

(2) The bid amount for each lead item in a product category included under the DMEPOS CBP for the first time must not exceed the unadjusted fee schedule amount for the lead item.

(3) Notwithstanding paragraph (b)(4) of this section, the bid amount for each lead item in a product category included in a prior competition, must not exceed, for the same CBA, the lesser of—

(i) The most recent SPA for the item plus 10 percent; or

(ii) The unadjusted fee schedule amount for the item.

(4) If it has been more than 1 year since a SPA was paid for the item in the prior competition, the bid amount must not exceed the lesser of the—

(i) Most recent SPA made for the item, as adjusted by the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) from the mid-point of the 12-month period the most recent SPA was in effect to the date that is 6 months prior to the date CMS announces the dates suppliers may register and submit bids under the current round of competition, plus 10 percent; or

(ii) Unadjusted fee schedule amount for the item.

(5) The bid amount for each lead item in a product category included in a prior competition but made under a bid for a new CBA, must not exceed the lesser of the—

(i) Adjusted fee schedule amount for the item plus 10 percent; or

(ii) Unadjusted fee schedule amount for the item.

* * * *

(9) The bid amount submitted for rental of class II continuous glucose monitors included as a lead item in a product category in a remote item delivery CBP for the first time must not exceed the payment amount that would otherwise apply to the monthly fee schedule amount for the supplies for the class II continuous glucose monitor under subpart D of this part plus the average of the purchase fee schedule amounts that would otherwise apply to the class II continuous glucose monitor for the areas included in the remote item delivery CBP divided by 60.

(10) The bids amount submitted for rental of insulin infusion pumps included as a lead item in a product category in a remote item delivery CBP for the first time must not exceed the nonrural payment amount that would otherwise apply to the supplies and accessories for the insulin infusion

pump under subpart D of this part, with the application of § 414.210(g), for a 1-month period plus the total nonrural rental fee schedule amounts that would otherwise apply to rental of the insulin pump for 13 months of continuous use under subpart D of this part, with the application of § 414.210(g), divided by 60.

(11) The bid amounts submitted for an OTS back brace or OTS knee brace included as a lead item in a product category in a remote item delivery CBP for the first time cannot exceed the average nonrural payment amount that would otherwise apply to the item under subpart D of this part, with the application of § 414.210(g), for the areas included in the remote item delivery CBP.

(12) The bids submitted for all other items included as a lead item in a product category in a remote item delivery CBP for the first time must not exceed the average payment amount that would otherwise apply to the item under subpart C, D, or Q of this part for the areas included in the remote item delivery CBP.

* * * * *

(g) * * *

(5) *Bid surety bond riders.* (i) Bid surety bonds submitted prior to the deadline for bid submission are reviewed to determine if they contain any deficiencies that would make the applicable bid(s) ineligible to receive a DMEPOS CBP supplier contract offer. CMS notifies the bidder of the deficiency(ies) and allow the bidder to submit a bid surety bond rider to rectify the deficiency(ies).

(ii) Bidding entities can submit a bid surety bond rider to correct the identified deficiency(s) applicable to any of the bid surety bond requirements outlined in paragraphs (g)(2)(i) and (ii) of this section. No other deficiency(ies) can be rectified by a bid surety bond rider.

(iii) Bidding entities notified of a bid surety bond deficiency have 10-business days after the date of such notice to submit a bid surety bond rider. The bidder must receive the bid surety bond rider from the authorized surety that issued the original bid surety bond.

■ 8. Section 414.414 is amended by revising paragraphs (d) introductory text (d)(1), (2)(ii)(B), (e), (f), and (h) to read as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(d) *Financial standards.* (1) *Financial document requirements.*

(A) By the close of the bid window, the bidding entity must, in accordance

with paragraph (d)(2) of this section, submit both a business credit report with a numerical credit score or rating unless the bidding entity is unable to generate a business credit report with a numerical credit score or rating because the bidding entity has not been in operation long enough to generate a numerical score or rating.

(B) A bidding entity that is unable to generate a business credit report with a numerical credit score or rating is required to submit a business credit report showing no data or insufficient information to generate a credit score, in addition to a personal credit report with a numerical credit score or rating from the bidding entity's Authorized Official or Delegated Official listed in CMS' PECOS.

(C) The bidding entity must submit the documentation described in paragraphs (d)(1)(A) and (B) of this section, along with the name of the bidding entity or Authorized Official or Delegated Official, as applicable, and the date each document was prepared not earlier than 90 calendar days prior to the opening of the bid window in a form and manner specified by CMS.

(D) The bidding entity must attest in the bidding system that it is submitting one bid that includes all commonly owned or commonly controlled locations, and that it will furnish the lead item and all non-lead items in the same competition.

(2) *Financial scoring methodology.* A credit report scoring list is published before the opening of the bid window in the round specific Request for Bids Instructions or a fact sheet or both which includes all of the following:

(i) The approved credit agencies from which a bidding entity must obtain a business credit report with a numerical credit score or rating.

(ii) The approved business credit reports and associated credit scores or ratings that must be submitted.

(iii) The scoring system that will be utilized to determine if a bidding entity met the financial sustainability threshold.

* * * * *

(2) * * *

(ii) * * *

(B) *For subsequent Round bids.* CMS has 90 days after the covered document review date to review the submitted covered documents and notify bidders of any covered documents that are missing or provide confirmation that all covered documents were received by the close of the bid window.

* * * * *

(e) *Evaluation of bids.* CMS evaluates composite bids submitted for a lead

item within a product category by doing all of the following:

(1) Calculating the number of suppliers selected to furnish the items and services in the competition in accordance with paragraph (h) of this section.

(2) Arraying the composite bids from the lowest composite bid price to the highest composite bid price.

(3) Selecting the number of suppliers and networks calculated under paragraph (e)(1) of this section that meet the requirements in paragraphs (b) through (d) of this section with the lowest composite bids.

(f) *Expected savings.* A DMEPOS CBP supplier's contract is not awarded for a competition under this subpart unless CMS determines that the SPA to be paid to contract suppliers for the lead item would be no greater than the lesser of—

(1) 110 percent of the adjusted fee schedule amount for the item, if applicable; or

(2) the unadjusted fee schedule amount for the item.

* * * * *

(h) *Sufficient number of contract suppliers.* (1) Notwithstanding paragraph (h)(1)(ii) of this section, for competitions included in the DMEPOS CBP in 2018 or 2023, the first time a competition is recomputed after 2023, the number of contract suppliers selected to furnish items and services in the competition is no more than double the number of contract suppliers that furnished at least 5 percent of total allowed services for the lead item furnished by contract suppliers to the applicable beneficiary population during 2018 or 2023, adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023, and rounded to the nearest whole number.

(i) CMS adjusts the number of contract suppliers selected in accordance with paragraph (h)(1)(i) of this section for a competition to ensure the number selected is—

(A) Not less than 50 percent of the total number of contract suppliers that furnished the lead item in 2018 or 2023 rounded up to the nearest whole number;

(B) More than 75 percent of the total number of contract suppliers that furnished the lead in 2018 or 2023 rounded down to the nearest whole number; and

(C) At least 2.

(2) For competitions included in the DMEPOS CBP in 2018 or 2023, after the first time a competition is recomputed after 2023, the number of contract suppliers selected to furnish items and

services is in the competition is equal to the number of contract suppliers CMS selected the first time the competition was recompeted after 2023, in accordance with paragraph (h)(1) of this section trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the most recent DMEPOS CBP supplier contract period, and rounded to the nearest whole number.

(3) For competitions not included in the DMEPOS CBP in 2018 or 2023—

(i) The first time a competition is conducted after 2023, the number of contract suppliers selected to furnish items and services is at least 2, but no more than 125 percent of the number of suppliers that furnished at least 3 percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, and rounded to the nearest whole number.

(ii) For all subsequent recompetes for the competition, the number of suppliers selected to furnish items and services is equal to the number of contract suppliers selected in the prior competition or recompetes, as applicable, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the most recent DMEPOS CBP supplier's contract period, and rounded to the nearest whole number.

■ 9. Section 414.416 is amended by revising paragraph (b)(1) to read as follows:

§ 414.416 Determination of competitive bidding payment amounts.

* * * * *

(b) *Methodology for setting payment amount.*

(1) Notwithstanding paragraphs (b)(2) through (4) of this section, a single payment amount for a lead item furnished under a competitive bidding program is equal to the 75th percentile of bid amounts submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. In cases where there is an odd number of winning contract suppliers, the SPA is determined by using the amount that is 75 percent between the two bid amounts, rounded to the nearest cent.

(2) The single payment amount for an item in a product category furnished under a competitive bidding program that is not a lead item for that product category (non-lead item) is equal to the single payment amount for the lead item in the same product category multiplied

by the ratio of the 2015 fee schedule amount for the non-lead item for the applicable area to which the fee schedule amount applies (State, District of Columbia, Puerto Rico, or United States Virgin Islands) to the 2015 fee schedule amount for the lead item for the same area.

(3) The single payment amount for an item included in a product category in a remote item delivery CBP furnished under a competitive bidding program that is not a lead item for that product category (non-lead item) is equal to the single payment amount for the lead item in the same product category multiplied by the ratio of the average 2015 fee schedule amount for the non-lead item for the applicable area to which the fee schedule amount applies (State, District of Columbia, Puerto Rico, or United States Virgin Islands) to the average 2015 fee schedule amount for the lead item for the same area.

(i)(A) The 2015 fee schedule amounts for a continuous glucose monitor and supplies are calculated using the 2025 fee schedule amounts and removing the covered items update factors for years 2016 through 2025 specified under section 1834(a)(14) of the Act.

(B) The 2015 fee schedule amounts for the bundled monthly rental of a continuous glucose monitor are calculated by adding the 2015 fee schedule amount for the supplies to the average of the 2015 fee schedule amounts for the purchase of a new continuous glucose monitor divided by 60 for the areas included in the remote item delivery CBP.

(ii) The 2015 fee schedule amount for the monthly supplies for a continuous glucose monitor owned by a beneficiary is calculated using the 2025 fee schedule amount and removing the covered item update factors for years 2016 through 2025 specified under section 1834(a)(14) of the Act.

(iii) The 2015 fee schedule amounts for the bundled monthly rental of an insulin infusion pump are calculated using the average 2015 fee schedule amounts for the insulin infusion pump multiplied by 10.5 and divided by 6 for the nonrural areas included in the remote item delivery CBP, and then adding the average 2015 fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by 9 for the nonrural areas included in the remote item delivery CBP plus the average 2015 fee schedule amounts for the weekly insulin pump supplies multiplied by 4 for the areas included in the remote item delivery CBP.

(iv) The 2015 fee schedule amounts for the monthly supplies and

accessories for an insulin infusion pump owned by a beneficiary is calculated using the average 2015 fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by 9 for the areas included in the remote item delivery CBR plus the average 2015 fee schedule amounts for the weekly insulin pump supplies multiplied by 4 for the areas included in the remote item delivery CBR.

■ 10. Section 414.422 is amended by adding paragraph (h) to read as follows:

* * * * *

(h) *Contract termination during a public health emergency (PHE) under section 319 of the Public Health Service Act.*

(1) If CMS determines in accordance with paragraph (h)(2) of this section, that due to a PHE, contract suppliers are unable to furnish certain items and services to beneficiaries in certain areas impacted by a PHE (PHE-impacted area) as required under their respective DMEPOS CBP supplier contracts, CMS may unilaterally terminate or modify each applicable DMEPOS CBP supplier's contract to allow any Medicare enrolled DMEPOS supplier to furnish the applicable items and services to Medicare beneficiaries in the PHE-impacted area. Depending on the geographic extent of the PHE, a PHE-impacted area may refer to entire CBA(s) or only certain areas within a CBA.

(i) If the items and services in the PHE-impacted area identified in accordance with paragraph (h)(2) of this section encompass all competitions referenced a DMEPOS CBP supplier's contract, CMS unilaterally terminates the DMEPOS CBP supplier's contract.

(ii) If the items and services in the PHE-impacted area identified in accordance with paragraph (h)(2) of this section encompass only a portion of the items and services and geographic areas referenced in a DMEPOS CBP supplier's contract, CMS unilaterally modifies the DMEPOS CBP supplier's contract to remove the contract supplier's obligation to furnish specified items and services in the PHE-impacted area, as well as CMS's obligation to pay for those items and services under the DMEPOS CBP supplier's contract.

(iii) After a termination or modification of all applicable DMEPOS CBP supplier contracts, CMS reverts back to the general fee-for-service program requirements set forth in 42 CFR part 414 Subpart D for the applicable competition(s) or defined area(s) within a CBA.

(2) CMS may remove items and services furnished in a PHE-impacted

area from the DMEPOS CBP when all of the following qualifying criteria are met:

- (i) The Secretary declares a PHE.
- (ii) CMS determines that verifiable evidence exists of a DMEPOS access problem for beneficiaries for a certain competition or defined area(s) within the competition's CBA.
- (iii) CMS determines that awarding additional DMEPOS CBP supplier contracts, per § 414.414(i), would not address the access concerns.
- (iv) CMS determines terminating or modifying each impacted DMEPOS CBP supplier's contract to exclude certain competition(s) or defined area(s) within the competition's CBA from the DMEPOS CBP would alleviate access concerns.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 11. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 12. Section 424.22 is amended by revising paragraph (a)(1)(v)(A) and removing paragraph (a)(1)(v)(C) to read as follows:

§ 424.22 Requirements for home health services.

* * * * *

- (a) * * *
- (1) * * *
- (v) * * *

(A) The face-to-face encounter must be performed by one of the following:
(1) A physician (as defined at § 484.2 of this chapter).

(2) A nurse practitioner (as defined at § 484.2 of this chapter).

(3) A clinical nurse specialist (as defined at § 484.2 of this chapter).

(4) A physician assistant (as defined at § 484.2 of this chapter).

(5) A certified nurse-midwife (as defined in section 1861(gg) of the Act) as authorized by State law.

* * * * *

■ 13. Section 424.57 is amended by—
■ a. Revising paragraphs (c)(10), (22), (23), (24), and (e)(1); and
■ b. Adding paragraph (h).

The revisions and addition read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

* * * * *

- (c) * * *

(10) Has a comprehensive liability insurance policy in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier.

(i) In the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations.

(ii) Failure to maintain required insurance at all times results in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed.

(iii) An authorized official of the supplier (as that term is defined in § 424.502) must sign the liability insurance policy.

* * * * *

(22)(i) All suppliers of DMEPOS and other items and services, and all of their locations whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited to enroll in and bill Medicare.

(ii) The accreditation must indicate the specific products and services for which the DMEPOS supplier is accredited in order for the supplier to receive payment for those specific products and services.

(iii) An accredited DMEPOS supplier may be denied enrollment, or its enrollment may be revoked, if CMS determines that it is not compliant with the DMEPOS quality standards.

(23) All DMEPOS suppliers must notify their DMEPOS accrediting organization when a new DMEPOS location is opened.

(24) All accredited DMEPOS suppliers must be surveyed and reaccredited at least once every 12 months.

* * * * *

- (e) * * *

(1) *Revocation.* CMS revokes a supplier's billing privileges if it is found not to meet the conditions or standards in paragraphs (b) and (c) of this section. Except as otherwise provided in this section, the revocation effective date is as specified in § 424.535.

* * * * *

(h) *Change in majority ownership.* A supplier must comply with the provisions of § 424.551 if it undergoes a change in majority ownership.

■ 14. Section 424.58 is amended by revising paragraphs (b) through (e) and adding paragraphs (f) through (o) to read as follows:

§ 424.58 Accreditation.

* * * * *

(b) *Definitions.* The following definitions apply to the provisions in this section:

Complaint means an allegation from any party and via any format that one of the DMEPOS accrediting organization's accredited DMEPOS suppliers may be non-compliant with

one or more DMEPOS quality standards or other applicable CMS requirement. The complaint need not involve actual or potential beneficiary harm.

Immediate family member means any person with whom the accrediting organization owner(s), surveyors or employees have a lineal or immediate familial or marital relationship, including all of the following:

- (i) A husband or wife.
- (ii) Birth or adoptive parent, child, or sibling.
- (iii) Stepparent, stepchild, stepbrother, or stepsister.
- (iv) Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law.
- (v) Grandparent or grandchild.
- (vi) Spouse of a grandparent or grandchild.

Immediate jeopardy means a situation in which the DMEPOS supplier's non-compliance with one or more DMEPOS quality standards or other applicable CMS requirement has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient or to the health and safety of the general public.

Reasonable assurance means that a DMEPOS accrediting organization has demonstrated to CMS' satisfaction all of the following:

(1) Its DMEPOS accreditation program requirements meet or exceed the Medicare program requirements.

(2) The DMEPOS suppliers that the DMEPOS accrediting organization accredits meet or exceed Medicare program requirements.

(3) The DMEPOS accrediting organization is compliant with all provisions of § 424.58.

Unannounced survey means both of the following:

(1) A survey that is conducted without any prior notice of any type (through any means of communication or forums) to the DMEPOS supplier to be surveyed such that the supplier does not expect the survey until the surveyors arrive.

(2) The DMEPOS accrediting organization schedules its surveys so that DMEPOS suppliers cannot predict when they will be performed.

(c) *Initial application procedures.* (1) *Required information.* An independent DMEPOS accrediting organization applying for initial approval of its DMEPOS accreditation program is required to furnish CMS with all the following information and materials to demonstrate that the DMEPOS accrediting organization provides reasonable assurance (as defined in paragraph (b) of this section) regarding its program.

(i) A list of the types of DMEPOS supplies, products, and services for which the organization is requesting approval.

(ii) A detailed comparison of the organization's accreditation requirements and standards with the applicable DMEPOS quality standards, such as a crosswalk.

(iii) A detailed description of the organization's operational, survey, and other accreditation processes to confirm that the DMEPOS suppliers it accredits meet or exceed the DMEPOS quality standards and Medicare program requirements. This must include all of the following:

(A) Procedures for performing unannounced surveys.

(B) Frequency of the surveys performed.

(C) Copies of the organization's survey forms.

(D) Guidelines and instructions to surveyors.

(E) Quality review processes for deficiencies identified with accreditation requirements.

(F) Dispute resolution processes and policies when there is a negative survey finding or decision.

(G) If the DMEPOS accrediting organization has the discretion to perform a survey in certain instances, how it determines whether to perform one. This must include a suggested methodology for sampling locations for surveys under a single tax identification number or organization.

(iv) Procedures used to notify DMEPOS suppliers of compliance or noncompliance with the accreditation requirements.

(v) Procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vi) Procedures for coordinating surveys with another DMEPOS accrediting organization if the organization does not accredit all supplies, products, and services the DMEPOS supplier provides.

(vii) Detailed professional information about the individuals who perform surveys for the DMEPOS accrediting organization, including the size and composition of accreditation survey teams for each type of DMEPOS supplier accredited, and the education and experience requirements surveyors must meet. The information must also include the following:

(A) The content and frequency of the continuing education training provided to survey personnel.

(B) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(C) Policies and procedures for a surveyor or institutional affiliate of the

DMEPOS accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which that individual or institution is professionally or financially affiliated.

(D) The organization's policies and procedures to avoid conflicts of interest and the appearance thereof involving individuals who conduct surveys or participate in accreditation decisions. This must include the organization's policies and procedures for all of the following:

(1) The separation of its consulting services from its accreditation services.

(2) Protecting the integrity of the DMEPOS accrediting organization's accreditation program (including the requirements of paragraphs (m) and (n) of this section).

(3) The prevention and handling of potential or actual conflicts of interest that could arise from situations in which a DMEPOS accrediting organization owner, surveyor, or employee has an interest in, or relationship with, a DMEPOS supplier to which the accrediting organization provides accreditation services. Such interests or relationships include, but are not limited to the following:

(i) Being employed as a DMEPOS accrediting organization surveyor.

(ii) Being employed by a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(iii) Having an ownership, financial, or investment interest in a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(iv) Serving as a director or of trustee for a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(v) Serving on a utilization review committee of a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(vi) Accepting fees or payments from a DMEPOS supplier or group of DMEPOS suppliers that is/are accredited by the DMEPOS accrediting organization.

(vii) Accepting fees for personal services, contract services, referral services, or for furnishing supplies to a DMEPOS supplier that is accredited by the DMEPOS supplier accrediting organization.

(viii) Providing consulting services to a DMEPOS supplier that the DMEPOS accrediting organization accredits.

(ix) Having any immediate family member (as defined in paragraph (b) of this section) engaged in any of the activities described in paragraphs (3)(i) through (viii) of this paragraph (D).

(x) Engaging in any activities during the course of the survey of the facility that would be or cause a conflict of interest.

(4) For notifying CMS when a conflict of interest is discovered.

(5) For the purposes of this section, a conflict of interest exists when a DMEPOS accrediting organization, the DMEPOS accrediting organization's successors, transferees, or assigns, the DMEPOS accrediting organization owner(s), surveyors, or employees, or the immediate family members of the DMEPOS accrediting organization owners(s), surveyors and other employees have an employment, business, financial or other type of interest in or relationship with a DMEPOS supplier that the DMEPOS accrediting organization accredits.

(E) The organization's policies and procedures for ensuring it has an adequate number of surveyors at all times.

(viii) Its processes for identifying and correcting deficiencies within its DMEPOS accreditation program.

(ix) A description of the organization's data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system. This must also include a detailed description of how the organization uses its data to ensure the compliance of its DMEPOS accreditation program with Medicare program requirements.

(x) Procedures for responding to, investigating, and (as applicable) closing out complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsman programs, the applicable National Provider Enrollment contractor, and CMS. This must also include a detailed outline of all of the following:

(A) The steps and research the DMEPOS accrediting organization will undertake in its initial review of the complaint as described in paragraph (e)(3) of this section.

(B) How the DMEPOS accrediting organization determines whether, in accordance with a complaint, non-compliance with a DMEPOS quality standard or other applicable CMS requirement exists, including the information it considers in its review and when and how it would take action against the DMEPOS supplier.

(xi) The organization's policies and procedures for notifying CMS of DMEPOS suppliers that fail to meet the

DMEPOS accrediting organization's requirements.

(xii) A description of all types, categories, and durations of accreditations offered by the organization.

(xiii) A list of the following:

(A) All currently accredited DMEPOS suppliers.

(B) The types, categories, and product codes of accreditation currently held by each DMEPOS supplier.

(C) The effective and expiration dates of each DMEPOS supplier's current accreditation.

(D) The upcoming survey cycles for all DMEPOS suppliers' accreditation surveys scheduled to be performed by the organization.

(xiv) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(xv) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform fully the required surveys and related activities.

(xvi) Information that demonstrates the DMEPOS accrediting organization's knowledge, expertise, and experience in DMEPOS.

(xvii) Information about the DMEPOS accrediting organization's ability to conduct timely reviews of accreditation applications.

(xviii) A description of the organization's accreditation decision-making process. This includes its policies and procedures for approving, denying, or terminating accreditation status for DMEPOS suppliers that fail to meet the DMEPOS accrediting organization's standards or requirements. This must include an explanation of the reasons for which it will deny or terminate a supplier's accreditation.

(xix) Policies and procedures for both of the following:

(A) Determining whether and when a survey is performed (for example, the DMEPOS supplier is providing a new item type). This includes the circumstances under which the DMEPOS accrediting organization will impose a corrective action plan (CAP) in lieu of performing a follow-up survey for an identified DMEPOS supplier deficiency.

(B) Ensuring that all onsite surveys are unannounced, including procedures that protect against unannounced surveys becoming known to the DMEPOS supplier before the visit.

(xx) Policies and procedures regarding when the DMEPOS accrediting organization will apply a CAP to a

DMEPOS supplier. This must include the following:

(A) The specific circumstances under which the DMEPOS accrediting organization will apply a CAP as opposed to, as applicable, denying or terminating accreditation and the rationale for why the accrediting organization believes a CAP in these situations is more appropriate.

(B) How the CAP is developed, implemented and enforced, including the following:

(1) How the DMEPOS accrediting organization determines whether a CAP is acceptable.

(2) The requirements of (and the timeframe and deadline for) the DMEPOS supplier's resumption of compliance.

(3) How the DMEPOS accrediting organization determines whether the DMEPOS supplier has resumed compliance and maintains compliance.

(4) The circumstances under which the DMEPOS accrediting organization will impose a CAP in lieu of performing a follow-up survey for an identified DMEPOS supplier deficiency.

(xxi) An explanation of the following:

(A) What the DMEPOS accrediting organization considers to be a DMEPOS supplier deficiency and how it defines the term deficiency.

(B) Whether the DMEPOS accrediting organization has different levels of DMEPOS supplier deficiencies.

(xxii) In performing the functions described in this section, its processes for both of the following:

(A) Detecting and addressing potential fraud, waste, and abuse by DMEPOS suppliers (including identifying the accrediting organization's definitions of the terms fraud, waste, and abuse).

(B) Reporting this activity to CMS and, as applicable, law enforcement.

(xxiii) A statement on the DMEPOS accrediting organization's letterhead that is signed and dated by the accrediting organization's chief executive officer (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) acknowledging that, as a condition for CMS approval or continued approval of a DMEPOS accrediting organization's accreditation program, the organization agrees to all of the following:

(A) Provide CMS, within 3 business days of CMS's request, both of the following:

(1) Any of the information described in paragraph (e)(1)(i) of this section.

(2) Any other information CMS deems necessary to facilitate its oversight of the DMEPOS accrediting organization's accreditation program.

(B) Provide CMS written notification when an accreditation survey or complaint investigation identifies an immediate jeopardy situation (as that term is defined in paragraph (b) of this section). Consistent with paragraph (e)(1)(iii) of this section, this notice must be provided within 2 business days of the finding.

(C) Provide written notification to CMS of any proposed changes to the DMEPOS accrediting organization's accreditation program and that it will not implement the proposed changes without prior written notice of continued program approval from CMS consistent with paragraph (e)(2) of this section.

(D) Notify CMS in writing of any decision to terminate, revoke, withdraw, or amend the accreditation status of a specific DMEPOS supplier within 3 business days of the date the organization took such action.

(E) Notify CMS of any decision to apply a CAP to a specific DMEPOS supplier within 10 calendar days of the decision. This notification must include the following:

(1) The reason for the decision.

(2) A detailed explanation and justification as to why the DMEPOS accrediting organization applied a CAP instead of, as applicable, denying or terminating the DMEPOS supplier's accreditation.

(3) The details of the DMEPOS supplier's CAP.

(F) Submit timely, accurate, and complete data to support CMS's evaluation of the DMEPOS accrediting organization's performance.

(1) Data to be submitted includes, but is not limited to, DMEPOS supplier identifying information, survey schedules, survey findings, and notices of accreditation decisions.

(2) The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(G) In response to a written notice from CMS to the organization of a change in the CMS quality standards, survey process, or other requirement, provide CMS with proposed corresponding changes in the organization's requirements for its DMEPOS accreditation program to ensure continued comparability with the CMS quality standards, survey process, and requirements. This includes compliance with the following requirements:

(1) Submission of the data required in paragraph (e)(7) of this section.

(2) The proposed changes must be submitted to CMS within 30 calendar

days of the date of the written CMS notice to the organization.

(3) The organization must not implement its proposed corresponding changes without prior CMS approval.

(H) Apply and adhere to in its accreditation activities any CMS-established—

- (1) Definition(s) of deficiency; and
- (2) Deficiency levels and categories.

(I) The DMEPOS accrediting organization will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(J) If CMS permits the DMEPOS accrediting organization to perform surveys via a sampling process, the accrediting organization:

- (1) Will submit to CMS its planned sampling methodology in detail; and
- (2) Will not undertake sampling until CMS has approved the accrediting organization's submitted methodology.

(K) Will not include the following as patient medical records in its DMEPOS supplier surveys:

- (1) Mock files.
- (2) Fictional patient records.
- (3) Simulated documentation.
- (4) Templates.
- (5) Duplicate patient records.

(L) Have a binding written agreement with each DMEPOS supplier the DMEPOS accrediting organization accredits regarding whether the accrediting organization, the supplier in question, or both will assume the costs of a survey that CMS directs the accrediting organization to perform in accordance with paragraph (e)(8)(ii) of this section.

(M) Submit all required information to CMS both before and after approval of its DMEPOS accreditation program in a truthful, accurate, and complete manner.

(N) Adhere to the requirements of this section at all times, including the policies, procedures, practices, and agreements it outlined in paragraph (c) of this section as part of its initial or reapproval application and any CMS-approved changes thereto under paragraph (e)(2) or (e)(7) of this section.

(2) *Additional information needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the organization's initial application, CMS notifies the organization and afford it an opportunity to provide the additional information.

(3) *Withdrawing an application.* A DMEPOS accrediting organization may withdraw its initial application for CMS' approval of its DMEPOS accreditation program at any time before CMS posts the notice described in paragraph (c)(6) of this section.

(4) *Reasons for denial.* CMS may deny a DMEPOS accrediting organization's application for any of the following reasons:

(i) The DMEPOS accrediting organization has failed to comply with all application, data, and agreement submission requirements outlined in paragraph (c) of this section.

(ii) The DMEPOS accrediting organization has failed to provide reasonable assurance (as defined in paragraph (b) of this section).

(iii) The current number of CMS-approved DMEPOS accreditation programs is sufficient to ensure the continued administration of CMS' DMEPOS accreditation program.

(iv) The DMEPOS accrediting organization's DMEPOS accreditation program was previously terminated, suspended, or placed on probation by CMS under, respectively, paragraph (h), (i), or (j) of this section.

(v) The DMEPOS accrediting organization, or any owner (as defined in § 424.502), managing employee (as defined in § 424.502), governing body member, W-2 or contracted surveyor, or W-2 or contracted health care or administrative or management services personnel thereof—

(A) Is excluded by the Office of Inspector General (OIG) from Medicare, Medicaid, and any other Federal health care program;

(B) Is debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA);

(C) Within the preceding 10 years—

- (1) Was convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries;
- (2) Has had a Medicare enrollment revoked under § 424.535;
- (3) Has had a license to provide health care suspended or revoked by any State licensing authority; or

(4) Has been suspended or terminated from participating in a Federal or State health care program.

(vi) The DMEPOS accrediting organization has submitted false or misleading information on its application in order to gain CMS approval or reapproval as a DMEPOS accrediting organization.

(vii) The AO is non-compliant with any provision in this section.

(viii) CMS otherwise determines that approval of the applicant as a DMEPOS AO would not be in the best interests of the Medicare program and its beneficiaries.

(5) *Notice of approval or denial of application.* CMS sends to the DMEPOS

accrediting organization a notice of its decision to approve or deny the application within 210 calendar days from the date CMS determines the accrediting organization's application is complete. The final notice specifies the following:

(i) The basis for the decision.

(ii) If applicable, the effective date of approval.

(iii) If applicable, the term of the approval (not to exceed 6 years).

(6) *Decision announcement.* CMS announces on its website its decision to approve or deny the DMEPOS accrediting organization's application.

(i) This announcement is posted within 210 calendar days from the date that CMS determines that the DMEPOS accrediting organization's application was complete.

(ii) If the application is approved, the posting states the approval's effective date (no later than the announcement's posting date) and length (6 years or less).

(7) *Term of approval.* CMS may approve a DMEPOS accreditation organization for any period up to a maximum of 6 years.

(d) *Reapproval process.* (1)(i) *Timeline for submission.* Except as stated in paragraph (d)(1)(ii) of this section, an approved DMEPOS accrediting organization that seeks to continue as such must apply for reapproval of accreditation no later than 9 months before the expiration of its current term of approval. If the organization fails to do so, CMS, at its discretion, may provide the organization an additional 30 days to reapply.

(ii) *Discretion to request reapproval applications.* CMS may require DMEPOS accrediting organizations to submit reapproval applications under paragraph (d) of this section any time after January 1, 2026. An application must be submitted within 60 calendar days of CMS' submission request. Failure to submit the application results in the termination of the DMEPOS accrediting organization's approval.

(2) *Submission of information and statements.* As part of its reapproval application, the DMEPOS accrediting organization must submit all information and statements identified in paragraph (c)(1) of this section. CMS may also request information under paragraph (c)(2) of this section.

(3) *Withdrawing an application.* A DMEPOS accrediting organization may withdraw its reapproval application for CMS' approval of its DMEPOS accreditation program at any time before CMS posts the notice described in paragraph (d)(6) of this section.

(4) *Denial reasons.* CMS may deny a DMEPOS accrediting organization's reapproval application for any of the reasons described in paragraph (c)(4) of this section.

(5) *Notice of approval or denial of application.* CMS sends a notice of its decision to approve or deny the DMEPOS accrediting organization's reapproval application within 210 calendar days from the date CMS determines the accrediting organization's reapproval application is complete. The final notice specifies the following:

- (i) The basis for the decision.
- (ii) The effective date.
- (iii) The term of the approval (not to exceed 6 years).

(6) *Decision announcement.* CMS announces on its website its decision to reapprove or deny the DMEPOS accrediting organization's reapproval application.

(i) This announcement is posted within 210 calendar days from the date that CMS determines that the DMEPOS accrediting organization's reapproval application was complete.

(ii) If the reapproval application is approved, the posting states the reapproval's effective date (no later than the announcement's posting date) and length (6 years or less).

(7) *Term of approval.* CMS may reapprove a DMEPOS accreditation organization for any period up to a maximum of 6 years.

(e) *Ongoing responsibilities of a CMS-approved DMEPOS accrediting organization.* A DMEPOS accrediting organization approved by CMS must undertake the following activities on an ongoing basis:

(1) *Submission of information.* (i) No later than the last day of each month, provide to CMS all the following in written format (either electronic or hard copy):

(A) Copies of all accreditation survey results and reports, together with any survey related information that CMS may require. This includes both of the following:

(1) CAPs and summaries of findings with respect to unmet CMS requirements.

(2) The instances where the DMEPOS accrediting organization had the discretion to perform a survey (for example, sampling) but decided not to, including the reason(s) for the organization's decision.

(B) Notice of all accreditation decisions.

(C) Notice of all resolved deficiencies.

(D) Information about any supplier of DMEPOS and other items and services against which the CMS-approved

DMEPOS accrediting organization has taken remedial or adverse action, including termination of the supplier's accreditation.

(ii) CMS may at any time request the DMEPOS accrediting organization to submit any of the information described in paragraph (e)(1)(i) of this section or any other data CMS deems necessary to facilitate its oversight of the accrediting organization's DMEPOS accreditation program. This information must be furnished to CMS within 3 business days of the request.

(iii) Within 2 calendar days of identifying an immediate jeopardy deficiency of a DMEPOS supplier, provide CMS with written notice of the deficiency and any adverse action implemented by the DMEPOS accrediting organization.

(2) *Standard or requirement changes.* Provide written notice of any proposed changes to its accreditation standards, requirements, or survey process. This includes the addition, modification, or removal of a new DMEPOS product service category to the list of categories for which the organization accredits DMEPOS suppliers.

(i) The notice must be submitted to CMS no less than 60 calendar days before the proposal's planned effective date. It must include the following:

(A) A detailed description of the changes and the rationale for them.

(B) A detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each.

(ii) CMS communicates to the DMEPOS accrediting organization in writing its approval or disapproval of the proposal within 30 calendar days of the proposed change's effective date.

(iii) CMS approval is required before the DMEPOS accrediting organization can implement the change. If the organization implements the changes before or without CMS' approval, CMS may terminate its approval of the accrediting organization.

(3) *Addressing complaints.* (i) Upon receipt of a complaint—

(A) Notify CMS in writing of the complaint no later than 5 calendar days after receipt;

(B) Using the DMEPOS accrediting organization's policies and procedures described in paragraph (c)(1)(x) of this section, perform an initial review of the complaint to determine whether, based on the complaint and any other information, the DMEPOS supplier may be non-compliant with one or more DMEPOS quality standards or other applicable CMS requirement; and

(C) Perform a survey of the DMEPOS supplier if the DMEPOS accrediting organization's initial review concludes that such non-compliance may exist. This survey must be performed no later than 21 calendar days after the accrediting organization received the initial complaint.

(ii) No later than 10 calendar days after completing the action in, as applicable, paragraph (e)(3)(i)(B) or (C) of this section, notify CMS in writing of the result of the initial review or, as applicable, the survey. The notice must include information regarding any action the DMEPOS accrediting organization took or plans to take with respect to the DMEPOS supplier, such as a termination of accreditation or a CAP.

(4) *CAPs.* Notify CMS in writing of any decision to apply a CAP to a specific DMEPOS supplier within 10 calendar days of the decision. This notification must include all of the following:

(i) The reason for the decision.

(ii) A detailed explanation and justification as to why the DMEPOS accrediting organization applied a CAP instead of, as applicable, denying or terminating the DMEPOS supplier's accreditation.

(iii) The details of the DMEPOS supplier's CAP (for example, deadline for compliance, the DMEPOS accrediting organization's plans for enforcement and ensuring compliance).

(5) *Denials and terminations.* (i) Notify CMS in writing of any decision to deny accreditation to (or terminate, revoke, withdraw, or amend the accreditation of) a DMEPOS supplier within 5 calendar days of the decision. This notification must include the reason for the denial or termination.

(ii)(A) Notwithstanding any other provision in this section, the DMEPOS accrediting organization must deny accreditation to (or terminate the accreditation of) a DMEPOS supplier if—

(1) The supplier does not meet the licensure requirements in § 424.57(c)(1)(ii);

(2) The supplier is not operational (as that term is defined in § 424.502);

(3) The supplier's location does not meet the accessibility requirements in § 424.57(c)(7)(i)(B);

(4) The supplier's Medicare enrollment is revoked due to non-compliance with one or more DMEPOS quality standards and the reenrollment bar under 424.535(c) has not expired; or

(5) Directed by CMS.

(B) If paragraph (ii)(A)(5) of this paragraph applies, the DMEPOS

accrediting organization must do the following:

(1) Deny or terminate the DMEPOS supplier's accreditation no later than 3 business days after receiving written notice from CMS to do so.

(2) Notify CMS in writing that it has taken this action within 5 business days of receiving the written notice from CMS.

(6) *Provide an annual summary of data related to accreditation.* Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(7) *Notification of change from CMS.* (i) Within 30 calendar days of receipt of a written notice from CMS to the organization of a change in the quality standards, survey process, or other requirement, provide CMS with proposed corresponding changes to the organization's requirements for its CMS-approved DMEPOS accreditation program to ensure continued comparability with the CMS quality standards, survey process, or other requirements. This includes all of the following:

(A) An acknowledgment of CMS's notification of the change.

(B) A revised cross walk reflecting the new requirements.

(C) An explanation of how the DMEPOS accrediting organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification it received from CMS.

(ii) The DMEPOS accrediting organization must not implement its proposed corresponding changes without prior CMS approval.

(8) *Performance of surveys.* (i) Except as otherwise directed or permitted in writing by CMS (for example, allowing sampling), the DMEPOS accrediting organization must—

(A) Perform a survey of all DMEPOS supplier locations for which the supplier seeks accreditation or reaccreditation with the DMEPOS accrediting organization. This includes, but is not limited to, accreditations for a new item type the supplier has not previously furnished or as required under § 424.551;

(B) Perform all surveys as unannounced surveys; and

(C) Not accredit the DMEPOS supplier before the survey is performed and the DMEPOS accrediting organization determines that the supplier is compliant with the quality standards.

(ii) CMS may, at any time, direct the DMEPOS accrediting organization to perform a survey of an accredited DMEPOS supplier or a group thereof.

Existence of an actual or suspected supplier deficiency is not a requirement for CMS to direct the performance of a survey of a supplier.

(iii) When performing a survey, the DMEPOS accrediting organization must also confirm that the DMEPOS supplier meets the licensure requirements in § 424.57(c).

(9) *Surveyor witnesses.* Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(10) *Data entry.* If directed by CMS, enter accreditation, survey, product code, and other data into a CMS-designated system.

(11) *Relationships.* The DMEPOS accrediting organization, or any owner (as defined in § 424.502), managing employee (as defined in § 424.502), governing body member, or any W-2 or contracted surveyor, health care, administrative, or management personnel thereof, must not have any of the following:

(i) A current exclusion by the OIG from Medicare, Medicaid, and any other Federal health care program.

(ii) A current debarment, suspension, or exclusion from participating in any other Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(iii) Within the preceding 10 years—

(A) A conviction of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries;

(B) A Medicare enrollment revocation under § 424.535;

(C) A suspension or revocation of a license to provide health care by any State licensing authority; or

(D) A suspension or termination from participating in a Federal or State health care program.

(f) *Continuing federal oversight of approved DMEPOS accrediting organizations.* CMS evaluates the performance of each CMS-approved DMEPOS accreditation program on an ongoing basis. Means of monitoring include, but are not limited to, the reviews identified in this paragraph.

(1) *Equivalency review.* CMS may, at any time, compare the DMEPOS accrediting organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes.

(2) *Validation survey of DMEPOS supplier.*

(i). *Survey scope.* CMS may survey suppliers of DMEPOS and other items and services accredited under this section in order to validate the DMEPOS accrediting organization's survey

process. Surveys can be comprehensive or focus on certain standards or requirements.

(ii) *Discovery of a deficiency.* If CMS discovers that a DMEPOS supplier is not in compliance with the DMEPOS supplier quality standards, CMS may revoke the supplier's enrollment or require the DMEPOS accrediting organization to perform a subsequent full accreditation survey at the accrediting organization's expense.

(iii) *Authorization.* A DMEPOS supplier selected for a validation survey must—

(A) Authorize the validation survey to take place; and

(B) Permit the CMS survey team to monitor the correction of any deficiencies found during the validation survey.

(iv) *Failure to authorize.* If a DMEPOS supplier selected for a validation survey fails to comply with the requirements of paragraph (f)(2)(iii) of this section, it is deemed to no longer meet the DMEPOS supplier quality standards and may have its enrollment revoked.

(v) *Non-compliance.* If a validation survey results in a finding that the DMEPOS supplier is not in compliance with one or more DMEPOS supplier quality standards, the supplier no longer meets the DMEPOS quality standards and may have its enrollment revoked.

(3) *Deficiencies.* (i) With respect to DMEPOS supplier compliance with the quality standards, CMS has the discretion to do all of the following:

(A) Define the term *deficiency*.

(B) Establish levels and categories of deficiencies.

(C) Revise the quality standards.

(ii) In its DMEPOS accreditation activities, the DMEPOS accrediting organization must apply and adhere to all of the following:

(A) Any CMS-established definition of deficiency.

(B) All CMS-established levels and categories of deficiencies.

(C) All CMS-established quality standards.

(4) *Review of DMEPOS accrediting organization.*

(i)(A) CMS may at any time and for any reason conduct a review of the DMEPOS accrediting organization's processes or performance to:

(1) Verify the organization's representations to CMS; or

(2) Assess the organization's compliance with its own policies and procedures, the provisions of this section, and all other CMS requirements.

(B) The scope, length, and timing of the review are within CMS' discretion. Evidence of the DMEPOS accrediting

organization's potential non-compliance with any element addressed in paragraph (f)(4)(i)(A)(2) of this section is not a prerequisite for performing a review.

(ii) Types of CMS reviews include, but are not limited, the following, and may be performed collectively or individually:

(A) Equivalency reviews under paragraph (f)(1) of this section.

(B) Conducting surveys of accredited DMEPOS suppliers under paragraph (f)(2) of this section.

(C) Examining the results of a DMEPOS accrediting organization's surveys of DMEPOS suppliers.

(D) Observing a DMEPOS accrediting organization's onsite surveys and other audits of DMEPOS suppliers.

(E) Conducting onsite inspections of the DMEPOS accrediting organization's operations and offices.

(F) Requesting and reviewing documents.

(G) Interviewing DMEPOS accrediting organization staff.

(H) Observing an accreditation organization's internal meetings concerning the accreditation process.

(g) *Voluntary termination of CMS-approved DMEPOS accreditation program.* (1) *Timing.* A DMEPOS accrediting organization may voluntarily terminate its CMS-approved accreditation program at any time. In doing so, the accrediting organization must do all of the following:

(i) Notify CMS of its decision to voluntarily terminate its approved DMEPOS accreditation program at least 120 calendar days in advance of the effective date of the termination.

(ii) Provide written notice at least 90 days in advance of the effective date of the termination to each of its accredited DMEPOS suppliers but not before notifying CMS of its decision in accordance with paragraph (g)(1)(i) of this section. The notice to each supplier must do the following:

(A) Describe the provisions in paragraph (g)(2) of this section regarding the expiration dates of the DMEPOS supplier's accreditation with the terminating DMEPOS accrediting organization.

(B) Inform the DMEPOS supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminating DMEPOS accrediting organization expires and the effective date of its accreditation with a different accrediting organization) may result in the revocation of its enrollment under § 424.535.

(2) *Supplier continuation of accreditation.* Unless the DMEPOS

supplier is otherwise determined to be non-compliant with the quality standards or other requirement for accreditation, the supplier's accreditation with the terminating DMEPOS accrediting organization remains in effect until the earlier of the following:

(i) The expiration of its current term of accreditation with the terminating DMEPOS accrediting organization.

(ii) The effective date of its accreditation with a different CMS-approved DMEPOS accrediting organization.

(h) *Involuntary termination.*

(1)(i) *Reasons for termination.* CMS may terminate a DMEPOS accrediting organization's approval for any of the following reasons:

(A) CMS determines that the DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(B) CMS determines that the continued approval of a CMS-approved DMEPOS accreditation program of any DMEPOS accrediting organization poses an immediate jeopardy to the patients of the entities accredited under that program, or the continued approval otherwise constitutes a hazard to the public health.

(C) CMS determines that the DMEPOS accrediting organization is non-compliant with any provision of this section. This includes, but is not limited to, situations where the accrediting organization has failed to do either of the following:

(1) Comply with a term or condition of a statement or agreement in paragraph (c)(1)(xxiii) of this section.

(2) Adhere to a policy, procedure, or practice it outlined under paragraph (c) of this section as part of its initial application or reapproval application or a CMS-approved change thereto under paragraph (e)(2) or (e)(7) of this section.

(D) There is a pattern or practice of the DMEPOS accrediting organization's accredited DMEPOS suppliers being revoked under § 424.535(a) for failing to comply with the quality standards.

(ii) CMS may terminate the DMEPOS accrediting organization's DMEPOS accreditation program effective the date of the letter described in paragraph (h)(2) of this section or any date thereafter.

(2) *Notification to DMEPOS accrediting organization.* CMS notifies the DMEPOS accrediting organization in writing of its decision to terminate the organization's accreditation approval. The notice must include all of the following:

(i) The reason for the termination.

(ii) The effective date of the termination.

(3) *Announcement.* CMS announces its termination decision (and the effective date thereof) on its website.

(4) *Notification to DMEPOS suppliers.* A DMEPOS accrediting organization whose CMS approval of its DMEPOS accreditation program has been terminated must notify, in writing, each of its accredited DMEPOS suppliers of the termination of CMS approval and its implications no later than 30 calendar days after the CMS website announcement described in paragraph (h)(3) of this section. The notice to each DMEPOS supplier must do all of the following:

(i) Describe the provisions in paragraph (h)(6) of this section regarding the expiration dates of the DMEPOS supplier's accreditation with the terminated DMEPOS accrediting organization.

(ii) Inform the DMEPOS supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminated DMEPOS accrediting organization expires and the effective date of its accreditation with a different DMEPOS accrediting organization) results in the revocation of its enrollment under § 424.535.

(5) *Collaboration.* If CMS terminates a DMEPOS accrediting organization's approved status, the DMEPOS accrediting organization must work collaboratively with CMS to direct its accredited DMEPOS suppliers to the remaining CMS-approved DMEPOS accrediting organizations within a reasonable period of time.

(6) *Continued accreditation.* (i) Unless the DMEPOS supplier is otherwise determined to be non-compliant with the quality standards or other requirement for accreditation, the supplier's accreditation with the terminated DMEPOS accrediting organization remains in effect until the earliest of one of the following:

(A) The expiration of its current term of accreditation with the terminated DMEPOS accrediting organization.

(B) The effective date of its accreditation with a different CMS-approved DMEPOS accrediting organization.

(C) A date specified by CMS based on the circumstances of the termination of the DMEPOS accrediting organization's approval.

(ii) In the event paragraph (h)(6)(i)(C) of this section is applicable, CMS notifies the affected DMEPOS supplier in writing of the deadline by which the supplier must be reaccredited.

(7) *Refunds.* If CMS terminates a DMEPOS accrediting organization's approved status, the terminated organization must refund to a DMEPOS supplier all payments the supplier made to the organization—

(i) As part of the DMEPOS supplier's request for accreditation or reaccreditation; and

(ii) Prior to the organization's notification to the DMEPOS supplier of its final decision regarding the supplier's request.

(i) *Suspension.* (1) *Reasons for suspension.* CMS may suspend a DMEPOS accrediting organization's approval for any of the following reasons:

(i) CMS determines that the DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(ii) CMS determines that the DMEPOS accrediting organization is non-compliant with any provision of this section. This can include, but is not limited to, situations where the DMEPOS accrediting organization has failed to do either of the following:

(A) Comply with a term or condition of a statement or agreement in paragraph (c)(1)(xxiii) of this section.

(B) Adhere to a policy, procedure, or practice it outlined under paragraph (c) of this section as part of its initial application or reapproval application or a CMS-approved change thereto under paragraph (e)(2) or (e)(7) of this section.

(iii) There is a pattern or practice of the DMEPOS accrediting organization's accredited DMEPOS suppliers being revoked under § 424.535 for failing to comply with the DMEPOS quality standards.

(2) *Components of a suspension.* (i) Except as otherwise specified or permitted by CMS, a DMEPOS accrediting organization may not perform any Medicare DMEPOS accreditation activities while suspended.

(ii) CMS determines the length of the suspension, which lasts no longer than 1 year. Upon the expiration of the suspension period, CMS either lifts the suspension or terminates the organization's approval in accordance with paragraph (h) of this section.

(iii) CMS may suspend the DMEPOS accrediting organization's DMEPOS accreditation program effective the date of the letter described in paragraph (i)(3) of this section or any date thereafter.

(3) *Notification to DMEPOS accrediting organization.* (i) CMS notifies the DMEPOS accrediting organization in writing of its decision to suspend the organization's accreditation

approval. The notice must include the following:

(A) The reason(s) for the suspension.

(B) The effective date and length of the suspension.

(C) The terms of the suspension.

(D) The steps the DMEPOS accrediting organization must take to have the suspension lifted.

(ii) No later than 3 calendar days after the date it receives the notice of suspension, the DMEPOS accrediting organization must notify CMS in writing its acknowledgment of receipt of such notice.

(iii) No later than 3 calendar days after receipt of such acknowledgment, CMS publishes on its website a notice of the organization's DMEPOS accreditation program.

(4) *Status of DMEPOS suppliers.* (i) The accreditation status of DMEPOS suppliers currently accredited by the suspended DMEPOS accrediting organization remains in effect through the length of the suspension unless—

(A) The DMEPOS supplier's current term of accreditation with the suspended DMEPOS accrediting organization expires during the suspension;

(B) The DMEPOS supplier is otherwise determined to be non-compliant with the quality standards or other requirement for accreditation; or

(C) CMS specifies a different accreditation termination date based on the circumstances of the suspension of the DMEPOS accrediting organization's DMEPOS accreditation program.

(ii)(A) If paragraph (i)(4)(i)(A) of this section applies, the DMEPOS supplier must be reaccredited by—

(1) Its current DMEPOS accrediting organization if the suspension has been lifted; or

(2) A different CMS-approved DMEPOS accrediting organization.

(B) If paragraph (i)(4)(i)(C) of this section applies, CMS notifies the affected DMEPOS supplier in writing of the deadline by which the supplier must be reaccredited.

(iii) Any lapse in the DMEPOS supplier's accreditation (including between the date its existing accreditation with the suspended DMEPOS accrediting organization expires and the effective date of its accreditation with a different accrediting organization) may result in the revocation of its enrollment under § 424.535(a).

(5) *Lifting of suspension.* (i) CMS lifts a DMEPOS accrediting organization's suspension if it determines all of the following:

(A) The reasons for the suspension no longer exist.

(B) The DMEPOS accrediting organization demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(C) The DMEPOS accrediting organization is in compliance with all provisions of this section.

(ii) If the suspension is lifted:

(A) CMS notifies the DMEPOS accrediting organization thereof in writing.

(B) No later than 3 calendar days after the date it receives the notice described in paragraph (i)(3)(iv)(A) of this section, the DMEPOS accrediting organization must notify CMS in writing its acknowledgment of receipt of such notice.

(C) No later than 3 calendar days after receipt of such acknowledgment, CMS publishes on its website a notice of the lifting of the suspension.

(6) *Refunds.* If CMS suspends a DMEPOS accrediting organization's DMEPOS accreditation program, the accrediting organization must refund to a DMEPOS supplier all payments the supplier made to the organization—

(i) As part of the DMEPOS supplier's request for accreditation or reaccreditation; and

(ii) Prior to the organization's notification to the DMEPOS supplier of its final decision regarding the supplier's request.

(7) *Multiple suspensions.* Nothing in this paragraph (i) prohibits CMS from suspending the organization's DMEPOS accreditation program more than once.

(j) *Probation.* (1) *Placement on probation.* CMS may place a DMEPOS accrediting organization's DMEPOS accreditation program on probation and require the organization's successful completion of a corrective action plan (CAP) if CMS determines any of the following:

(i) The DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(ii) The DMEPOS accrediting organization is non-compliant with any provision of this section. This can include, but is not limited to, situations where the accrediting organization has failed to—

(A) Comply with a term or condition of a statement or agreement in § 424.58(c)(1)(xxiii); or

(B) Adhere to a policy, procedure, or practice it outlined under § 424.58(c) as part of its—

(1) Initial or reapproval application; or

(2) A CMS-approved change thereto under paragraph (e)(2) or (e)(7) of this section.

(iii) There is a pattern or practice of the DMEPOS accrediting organization's

accredited DMEPOS suppliers being revoked under § 424.535(a) for failing to comply with the quality standards.

(iv) The DMEPOS organization's period of suspension under paragraph (i) of this section has expired and CMS determines that a subsequent probationary period and CAP are warranted.

(2) *Notification to accrediting organization.* (i) CMS notifies the DMEPOS accrediting organization in writing of the probation. The notice must include the following:

(A) The reason(s) for CMS' decision.

(B) The length of the probationary period, which must not exceed 1 year.

(C) The terms of the CAP.

(D) The requirements and deadline for achieving compliance.

(E) A description of how CMS will monitor the DMEPOS accrediting organization's efforts to resume compliance (for example, requests for information, surveys).

(ii) Except as otherwise prescribed in the CAP, the DMEPOS accrediting organization may continue its accreditation activities as normal.

(3) *Conclusion of period.* (i) At the conclusion of the probationary period, CMS notifies the DMEPOS accrediting organization in writing of the following:

(A) Whether the DMEPOS accrediting organization is compliant with all requirements of this section.

(B) The reason for the determination in paragraph (j)(3)(i)(A) of this section.

(C) The consequences of the determination (for example, termination or suspension of accreditation, successful completion of and cessation of the probationary period and CAP).

(ii) If CMS determines that the DMEPOS accrediting organization has resumed compliance with all requirements of this section, CMS may do all of the following:

(A) Send the notice described in paragraph (j)(3)(i) of this section.

(B) Terminate the probationary period.

(C) End the CAP before the conclusion of the assigned probationary period.

(k) *Noncompliance actions.* (1) CMS may impose a certain action in paragraph (h), (i), or (j) of this section in lieu of another such action specified in paragraph (h), (i), or (j) of this section if the same ground(s) for the action exists.

(2) CMS may terminate—

(i) A probation period (either before or in accordance with the probationary period's original expiration date) and impose a suspension or termination if grounds for either action exist.

(ii) A suspension (either before or in accordance with the suspension's original expiration date) and impose a termination if a basis for doing so exists.

(l) *Reconsiderations and rebuttals.*

(1) *Reconsiderations.* (i) A DMEPOS accrediting organization may request a reconsideration under part 498 of the following CMS initial determinations identified in § 498.3(b)(21) and (22):

(A) Denial of the DMEPOS accrediting organization's application for initial approval of its DMEPOS accreditation program under § 424.58(c)(4).

(B) Denial of the DMEPOS accrediting organization's application for reapproval of its DMEPOS accreditation program under § 424.58(d)(4).

(C) Termination of the DMEPOS accrediting organization's approval of its DMEPOS accreditation program under § 424.58(h)(1).

(2) *Rebuttals.* (i)(A) If a DMEPOS accrediting organization receives notice from CMS that its DMEPOS accreditation program has been suspended or placed on probation in accordance with paragraph (i) or (j) of this section, the DMEPOS accrediting organization has 15 calendar days from the date of the written notice of the suspension or probation to submit a rebuttal to CMS.

(B) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (l)(2)(i)(A) of this section.

(ii) A rebuttal submitted under this section must—

(A) Be in writing;

(B) Specify the facts or issues about which the DMEPOS accrediting organization disagrees with CMS' determination, as well as the reasons for disagreement;

(C) Submit all documentation the DMEPOS accrediting organization wants CMS to consider in its review of its determination; and

(D) Be submitted in the form of a letter that is signed and dated by the DMEPOS accrediting organization's CEO (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) or a legal representative (as defined in § 498.10 of this chapter).

(1) If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the accrediting organization; this statement would be sufficient to constitute notice of such authority.

(2) If the legal representative is not an attorney, the accrediting organization must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the accrediting organization's CEO (or similar official with authority to commit the organization to adhere to Medicare

laws and regulations) or a legal representative.

(iii) The DMEPOS accrediting organization's failure to submit a rebuttal that is both timely under paragraph (l)(2)(i) of this section and fully compliant with all of the requirements of paragraph (l)(2)(ii) of this section constitutes a waiver of all rebuttal rights under this section.

(iv) Upon receipt of a timely and compliant rebuttal, CMS reviews the rebuttal to determine whether the imposition of the suspension or probation is correct.

(v) CMS is not required to delay the imposition of the suspension or probation pending the completion of the CMS review described in paragraph (l)(2)(iv) of this section.

(vi) A determination made under paragraph (i) or (j) of this section is not an initial determination under § 498.3(b) of this chapter and therefore not appealable.

(m) *Restrictions on consulting.* (1) *Definition.* For purposes of this paragraph (m) only, the terms *consulting* and *consulting services* mean those services provided by a DMEPOS accrediting organization (or its consulting division or separate business entity (such as a company or corporation) that provides such services) for the review of a DMEPOS supplier's standards, processes, policies, and functions for compliance with the accrediting organization's standards, the DMEPOS quality standards, or other Medicare requirements through simulation of a real survey, such as a mock survey, with comprehensive written reports of findings and early intervention and action to correct deficiencies prior to an actual accreditation survey.

(2) *Prohibitions.* Except as provided in paragraph (m)(3) of this section, an accrediting organization or its consulting division or separate business entity (such as a company or corporation that provides consulting) may not provide consulting services in the following instances:

(i) To any new DMEPOS supplier before the initial accreditation survey has been completed.

(A) For purposes of this paragraph, the term "initial survey" means the first accreditation survey performed of a supplier by a DMEPOS accrediting organization that has not previously received accreditation services from that accrediting organization.

(B) If a supplier is voluntarily or involuntarily terminated from the services of a DMEPOS accrediting organization and later retains the services of the same or a new DMEPOS

accrediting organization, the first accreditation survey performed by the same or new DMEPOS accrediting organization of that supplier would be considered an initial accreditation survey.

(ii) To a DMEPOS supplier that the DMEPOS accrediting organization accredits within 6 months prior to the next scheduled re-accreditation survey of that supplier. For purposes of this paragraph, the term “re-accreditation survey” means any subsequent accreditation survey performed by the accrediting organization following the initial survey.

(iii) To a DMEPOS supplier to which the DMEPOS accrediting organization provides accreditation services, in response to a complaint received by the accrediting organization regarding that supplier.

(3) *Circumstances permitting consulting.* A DMEPOS accrediting organization, its consulting division, or separate business entity, such as a company or corporation that provides consulting, may provide consulting to the DMEPOS suppliers it accredits only under the following circumstances:

(i) During the 6-month period after an initial or re-accreditation survey is performed.

(ii) To address complaints received and investigated by CMS or its contractor regarding a DMEPOS accrediting organization’s accredited DMEPOS supplier in which one or more immediate jeopardy deficiencies or grounds for revocation of enrollment under § 424.535 are identified. Such consulting by an accrediting organization may occur only after CMS or the CMS contractor investigation is completed and must only address those issues identified in the investigation.

(iii) Consulting services provided to DMEPOS suppliers that the DMEPOS accrediting organization does not accredit at the time the consulting services are furnished.

(iv) General education provided by the DMEPOS accrediting organization about its DMEPOS accreditation program.

(4) *Submission of report.* The DMEPOS accrediting organization must provide to CMS upon CMS’ request and with each initial and reapproval application under paragraphs (c) and (d) of this section a report containing the following information:

(i) Whether the DMEPOS accrediting organization or an associated consulting division or company established by the accrediting organization provides consulting services.

(ii) The names, National Provider Identifiers, and addresses of all

DMEPOS suppliers to which the DMEPOS accrediting organization or its associated consulting division or company has provided consulting services during the previous 6-month period.

(iii) The dates the consulting services were provided to each DMEPOS supplier.

(iv) Whether the DMEPOS accrediting organization has ever provided, or is currently providing, accreditation services to any DMEPOS supplier listed in this report.

(v) For each DMEPOS supplier listed in this report, the date—

(A) Of the most recent accreditation survey performed; and

(B) That the next re-accreditation survey is due to be performed.

(vi) A description of the consulting services provided to each DMEPOS supplier listed in this report.

(5) *Consulting firewall policies and procedures.* (i) A DMEPOS accrediting organization, its consulting division, or separate business entity (such as a company or corporation that provides consulting services to the DMEPOS suppliers the accrediting organization accredits) must have and adhere to written consulting policies and procedures, which, at a minimum, must include the following:

(A) The DMEPOS accrediting organization’s consulting services must be provided by a separate division of the accrediting organization or separate business entity, such as a company or corporation, that is separate from the accrediting organization’s accreditation division.

(B) A DMEPOS accrediting organization’s consulting division or separate business entity must maintain separate staff from that of the accrediting organization’s accreditation divisions to ensure that the consulting division staff do not perform the accrediting organization’s accreditation division functions and that the accrediting organization’s accreditation division staff do not perform consulting division functions.

(C) A DMEPOS accrediting organization’s accreditation staff and surveyors are prohibited from marketing the accrediting organization’s consulting services to the accrediting organization’s accreditation clients.

(ii) A DMEPOS accrediting organization that provides consulting services must submit its written consulting firewall policies and procedures to CMS by a date specified by CMS and with each application submitted seeking initial CMS approval or reapproval of their DMEPOS accreditation programs.

(n) *Conflicts of interest.*

(1) *General prohibition regarding relationships.* (i) If a DMEPOS

accrediting organization owner, surveyor, or employee (currently or within the previous 2 years) has or had an interest in or relationship (as described in paragraph (c)(1)(vii)(D) of this section) with a DMEPOS supplier that is accredited by the DMEPOS accrediting organization, the accrediting organization owner, surveyor, or employee is not permitted to do any of the following:

(A) Participate in the survey of that DMEPOS supplier.

(B) Have input into the results of the survey and accreditation for that DMEPOS supplier.

(C) Have involvement with the pre- or post-survey activities for that DMEPOS supplier.

(D) Have contact with or access to the records for the survey and accreditation of that DMEPOS supplier.

(ii) For purposes of paragraph (n)(1) of this section, the term “immediate family member” has the same meaning as that term is defined in paragraph (b) of this section.

(iii) CMS may request at any time outside of the initial approval and reapproval processes that the DMEPOS accrediting organization furnish any and all information required under paragraph (c)(1)(vii)(D) of this section.

(2) An entity may not serve as a CMS-approved DMEPOS accrediting organization if it is currently a CMS contractor (or an owner or subsidiary thereof (regardless of the ownership percentage involved)) with any oversight responsibility of DMEPOS suppliers.

(o) *Change of ownership.* A DMEPOS accrediting organization that wishes to undergo a change of ownership is subject to the requirements of § 488.5(f).

* * * * *

§ 424.205 [Amended]

■ 15. Section 424.205 is amended by—

■ a. In paragraph (a) in the definition of “Coach eligibility end date”, removing the phrase “paragraph (d)(5)” and adding in its place the phrase “paragraph (c)(5)”.

■ b. In paragraph (b)(4), removing the phrase “paragraph (d)(5)” and adding in its place the phrase “paragraph (c)(5)”.

■ c. In paragraph (b)(6), removing the phrase “paragraph (d)” and adding in its place the phrase “paragraph (c)”;

■ d. In paragraph (c)(3),

■ i. Removing the phrase “paragraph (d)(5)” and adding in its place the phrase “paragraph (c)(5)”;

■ ii. Removing the phrase “paragraph (e)(1)” and adding in its place the phrase “paragraph (d)(1)”;

- e. In paragraph (c)(6), removing the phrase “paragraph (d)(4)” and adding in its place the phrase “paragraph (c)(4)”;
- f. In paragraph (c)(8), removing the phrase “paragraph (d)(8)(i)” and adding in its place the phrase “paragraph (c)(8)(i)”;
- g. In paragraph (c)(8)(ii),
- i. Removing the phrase “paragraph (d)(8)(i)(B)” and adding in its place the phrase “paragraph (c)(8)(i)(B)”;
- ii. Removing the phrase “paragraph (d)(8)(i)(C)” and adding in its place the phrase “paragraph (c)(8)(i)(C)”;
- h. In paragraph (c)(10), removing the phrase “paragraph (d)(8)” and adding in its place the phrase “paragraph (c)(8)”;
- i. In paragraph (c)(11)(iii), removing the phrase “paragraph (d)” and adding in its place the phrase “paragraph (c)”;
- j. In paragraph (c)(12), removing the phrase “paragraph (g)” and adding in its place the phrase “paragraph (f)”;
- k. In paragraph (c)(15), removing the phrase “paragraph (g)” and adding in its place the phrase “paragraph (f)”;
- l. In paragraph (d)(2),
- i. Removing the phrase “paragraph (e)(1)” and adding in its place the phrase “paragraph (d)(1)”, and
- ii. Removing the phrase “paragraph (d)(5)” and adding in its place the phrase “paragraph (c)(5)”;
- m. In paragraph (g)(1),
- i. Removing the phrase “§ 424.530(a)(1)” and adding in its place adding “§ 424.530(a)(1) or § 424.530(a)(18)” each time it appears;
- ii. Removing the phrase “§ 424.535(a)(1)” and adding in its place adding “§ 424.535(a)(1) or § 424.535(a)(23)” each time it appears;
- n. In paragraph (g)(1)(i), removing the phrase “paragraph (h)(1)(i)” and adding in its place the phrase “paragraph (g)(1)(i)” each time it appears;
- o. In paragraph (g)(1)(ii),
- i. Removing the phrase “paragraph (d)” and adding in its place the phrase “paragraph (c)”;
- ii. Removing the phrase “paragraph (h)(1)(ii)” and adding in its place the phrase “paragraph (g)(1)(ii)” each time it appears;
- p. In paragraph (g)(1)(v)(A), removing the reference “§ 424.205(d)(3)” and adding in its place the reference “§ 424.205(c)(3)”;
- q. In paragraph (g)(1)(v)(B), removing the phrase “paragraph (h)(1)(v)” and adding in its place the phrase “paragraph (g)(1)(v)” each time it appears.
- X. Section 424.502 is amended by revising the definition of “Deactivate” to read as follows:

§ 424.502 Definitions.

* * * * *

Deactivate means, except in the situations described in § 424.547, that the provider or supplier’s billing privileges were stopped, but can be restored upon the submission of updated information.

* * * * *

- 16. Section 424.510 is amended by—
- a. In paragraph (d)(2)(iii) introductory text removing the phrase “including—” and adding in its place the phrase “including the following:”;
- b. In paragraph (d)(2)(iii)(A) removing the phrase “; and” and adding in its place “.”; and
- c. Adding paragraphs (d)(2)(iii)(C) and (d)(10).

The additions read as follows:

§ 424.510 Requirements for enrolling in the Medicare program.

* * * * *

(d) * * *

(2) * * *

(iii) * * *

(C) Any other documentation needed to verify and confirm the information furnished on the enrollment application. This includes, but is not limited to, documentation regarding the provider’s or supplier’s ownership or management.

* * * * *

(10) All providers and suppliers are legally responsible for the accuracy, completeness, and truthfulness of all information they provide on or with their applications, regardless of whether another party completed the application.

* * * * *

- 17. Section 424.516 is amended by revising paragraph (e)(1) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(e) * * *

(1) Within 30 days for a change of ownership or control (including changes in authorized official(s) or delegated official(s)), an adverse legal action, or a change, addition, or deletion of a practice location.

* * * * *

- 18. Section 424.522 is amended by revising paragraph (a) to read as follows:

§ 424.522 Additional effective dates.

(a)(1) The effective date of a reassignment of benefits under § 424.80 is the later of the dates identified in § 424.520(d)(1)(i) and (ii).

(2) Retrospective billing in accordance with a reassignment of benefits and as described in § 424.521(a)(1) is

permissible if the circumstances in § 424.521(a)(1) are applicable.

* * * * *

§ 424.530 [Amended]

- 19. Section 424.530 is amended by—
- a. In paragraph (a)(11)(ii), removing the word “drugs” and adding in its place the phrase “one or more drugs”;
- b. In paragraph (a)(18)(v), removing the phrase “or (d)” and adding in its place the phrase “or (c)”.
- 20. Section 424.535 is amended by—
- a. In paragraph (a)(13)(ii), removing the word “drugs” and adding in its place the phrase “one or more drugs”;
- b. In paragraph (a)(14) introductory text, removing the phrase “Part B or D drugs” and adding in its place the phrase “Medicare-covered drugs”;
- c. In paragraph (a)(23)(v), removing the phrase “or (d)” and adding in its place the phrase “or (c)”;
- d. Adding paragraphs (a)(8)(i)(D) and (8)(iii);
- e. Revising paragraph (g)(1) introductory text;
- f. Redesignating paragraph (g)(2)(viii) as paragraph (g)(2)(xv);
- g. Adding new paragraphs (g)(2)(viii) through (xiv).
- h. Revising newly redesignated paragraph (g)(2)(xv)(D);

The revisions and additions read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

* * * * *

(a) * * *

(8) * * *

(i) * * *

(D) The beneficiary attests that the item(s) or service(s) identified on the provider’s or supplier’s claim or claims was not or were not rendered or furnished.

* * * * *

(iii) The effective date of a revocation under paragraph (a)(8) of this section is—

(A) For revocations under paragraph (a)(8)(i) of this section, the earliest date of service on the claim or claims that is or are triggering the revocation; and

(B) For revocations under paragraph (a)(8)(ii), the last date of service on the claims in question.

* * * * *

(g)(1) Except as described in paragraphs (a)(8)(iii), (g)(2), and (3) of this section, a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier.

* * * * *

(2) * * *

(viii) For revocations based on a lapse in the IDTF's comprehensive liability insurance under § 410.33(g)(6), the date the insurance lapsed.

(ix) For revocations based on the provider's or supplier's submission of false or misleading information on the enrollment application, the date the application's certification statement was signed.

(x) For revocations based on the provider's or supplier's failure to timely report a change of ownership or adverse legal action, or a change, addition, or deletion of a practice location, the day after the date by which the provider or supplier was required to report the change, addition, or deletion.

(xi) For revocations based on the surrender of the provider's or supplier's provider's Drug Enforcement Administration certificate of registration in response to a show cause order, the date the certificate was surrendered.

(xii) For revocations based on a State's suspension or revocation of the physician's or practitioner's ability to prescribe one or more drugs, the date of the suspension or revocation.

(xiii) For revocations of any of the provider's or supplier's other enrollments under paragraph (i) of this section, the effective date of the revocation that triggered the revocation(s) of the other enrollment(s).

(xiv) For revocations based on a DMEPOS supplier's non-compliance with a condition or standard in § 424.57(b) or (c), respectively, the date on which the non-compliance began.

(xv) * * *

(D) For all standard violations not addressed in paragraph (g)(2) of this section, the effective date in paragraph (g)(1) of this section applies if the effective date in paragraph (g)(3) of this section does not.

* * * * *

§ 424.540 [Amended]

■ 21. Section 424.540 is amended in paragraph (a)(8) by removing the phrase "HHA change" and adding in its place the phrase "HHA, hospice, or DMEPOS supplier change".

■ 22. Section 424.541 is amended by—

■ a. In paragraph (a)(5), removing the phrase "60-day period" and adding in its place the phrase "CMS-assigned stay period"; and

■ b. Revising paragraphs (a)(1)(i), (a)(2)(ii)(B)(2), and (3).

The revisions read as follows:

§ 424.541 Stay of enrollment.

(a) * * *

(1) * * *

(i) Is non-compliant with at least one enrollment requirement in Title 42.

(This includes situations where its change of information or revalidation application was rejected under § 424.525(a)(1) or (2).)

* * * * *

(2) * * *

(ii) * * *

(B) * * *

(2) The stay ends (as described in paragraph (a)(5) of this section) on or before the expiration of the originally designated stay period.

* * * * *

(3)(i) The effective date of a stay of enrollment is, as applicable—

(A) The date on which the provider's or supplier's non-compliance began; or

(B) The date on which the provider's or supplier's change of information or revalidation application was rejected under § 424.525.

(ii) CMS may establish a stay of enrollment for any period up to a maximum of 60 days.

* * * * *

■ 23. Adding § 424.547 to read as follows:

§ 424.547 Deactivation based on ordering, certifying, or referring services and items.

(a)(1) CMS may deactivate a physician's or practitioner's ability to order, certify, or refer the Medicare services and items identified in § 424.507(a) and (b) if the individual:

(i) Is enrolled via the Form CMS–855O application solely to order, certify, or refer Medicare services or items; and

(ii) Has not been listed as the ordering, certifying, or referring individual on a Medicare Part A or B claim received in the previous 12 consecutive months.

(2) For purposes of this section only, the term "deactivate" means that the physician's or practitioner's ability to order, certify, or refer Medicare services or items has been stopped but can be restored upon the submission of updated information.

(b)(1) For a deactivated physician or practitioner to reactivate an ability to order, certify, or refer Medicare services and items, the individual must recertify that the enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in this title.

(2) Notwithstanding paragraph (b)(1) of this section, CMS may, for any reason, require a deactivated physician or practitioner to, as a prerequisite for reactivating the ability to order, certify, or refer, submit a complete Form CMS–855O application.

(c) The effective date of a reactivation of an ability to order, certify, or refer

Medicare services and items under this section is the date on which the Medicare contractor received the individual's reactivation submission that was processed to approval.

(d) A physician or practitioner may not order, certify, or refer the Medicare services or items described in § 424.507(a) and (b) while deactivated under this section.

■ 24. Adding § 424.551 to read as follows:

(a) *Definition.* For purposes of this section only, a *change in majority ownership* occurs when an individual or organization acquires more than a 50 percent direct ownership interest in a DMEPOS supplier during the 36 months following the DMEPOS supplier's initial enrollment into the Medicare program or the 36 months following the DMEPOS supplier's most recent change in majority ownership (including asset sale, stock transfer, merger, and consolidation). This includes an individual or organization that acquires majority ownership in a DMEPOS supplier through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the DMEPOS supplier's most recent change in majority ownership.

(b) *General principle.* Unless an exception in paragraph (c) of this section applies, if there is a change in majority ownership of a DMEPOS supplier by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the DMEPOS supplier's initial enrollment in Medicare or within 36 months after the DMEPOS supplier's most recent change in majority ownership, the Medicare billing privileges do not convey to the new owner. The prospective owner of the DMEPOS supplier must instead do both of the following:

(i) Enroll in the Medicare program as a new DMEPOS supplier under the provisions of § 424.510.

(ii) Undergo a survey by, and obtain a new accreditation from, a CMS-approved DMEPOS accrediting organization in accordance with §§ 424.57 and 424.58.

(c) *Exceptions.* The following situations are exceptions to the requirements of paragraph (b) of this section:

(i) A DMEPOS supplier's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

(ii) The owners of the existing DMEPOS supplier are changing the

DMEPOS supplier's current business structure (for example, from a corporation to a partnership (general or limited); from a limited liability company (LLC) to a corporation; or from a general or limited to an LLC) and the owners remain the same.

(iii) An individual owner of the DMEPOS supplier dies.

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 25. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

§ 455.416 [Amended]

■ 26. Section 455.416 is amended in paragraph (c) by removing the phrase “of the *Act* and under the” and adding in its place the phrase “of the *Act* or under the”.

PART 484—HOME HEALTH SERVICES

■ 27. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

§ 484.45 [Amended]

■ 28. Section 484.45 is amended in paragraph (a) by removing the word “beneficiary” and adding in its place the word “patient”, each time it appears.

§ 484.55 [Amended]

■ 29. Section 484.55 is amended in paragraph (d)(1)(i) by removing the phrase “Beneficiary elected transfer;” and adding in its place the phrase “Elected transfer;”.

■ 30. Section 484.245 is amended by revising paragraph (d)(4) and adding paragraphs (d)(5) and (6) to read as follows:

§ 484.245 Requirements under the Home Health Quality Reporting Program (HH QRP).

* * * * *

(d) * * *

(4)(i) CMS notifies the HHA, in writing, of its final decision regarding any reconsideration request through at least one of the following methods:

(A) CMS designated data submission system.

(B) The United States Postal Service.

(C) Email from the CMS Medicare Administrative Contractor (MAC).

(ii) CMS grants a timely request for reconsideration, and reverses an initial finding of non-compliance, only if CMS determines that the HHA was in full compliance with the HH QRP requirements for the applicable program year.

(6)(i) An HHA may request, and CMS may grant, an extension to file a reconsideration request if, during the period to request a reconsideration as set forth in paragraph (d)(2) of this section, the HHA was affected by an extraordinary circumstance beyond the control of the HHA (for example, a natural or man-made disaster).

(ii) HHAs must submit the reconsideration extension request no later than 30 calendar days from the date of the written notification of noncompliance.

(iii) The reconsideration extension request must—

(A) Be submitted to CMS via email to CMS HHAPU reconsiderations at HHAPUReconsiderations@cms.hhs.gov; and

(B) Contain all the following information:

(1) The CCN for the HHA

(2) The business name of the HHA.

(3) The business address of the HHA.

(4) Contact information for the HHA's chief executive officer or designated personnel, including the name, telephone number, title, email address, and physical mailing address, which may not be a post office box.

(5) A statement of the reason for the request for the extension.

(6) Evidence of the impact of extraordinary circumstances, including, for example, photographs, newspaper articles, and other media.

(6) CMS notifies the HHA in writing of its final decision regarding the HHA's request for an extension to file a reconsideration of noncompliance request via an email from CMS.

* * * * *

■ 31. Section 484.358 is amended by adding paragraph (i) to read as follows:

§ 484.358 HHVBP Measure removal factors.

* * * * *

(i) It is not feasible to implement the measure specifications.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 32. The authority for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7j, and 1395hh.

■ 33. Section 498.3 is amended by adding paragraphs (b)(21) and (22) to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *

(21) A denial of a DMEPOS accrediting organization's approval or re-approval under § 424.58(c)(4) or (d)(4) of this chapter, respectively.

(22) An involuntary termination of a DMEPOS accrediting organization's approved DMEPOS accreditation program under § 424.58(h)(1).

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS-1830-P]

RIN 0938-AV52

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and revise the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2026. This rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, this rule proposes to update requirements for the ESRD Quality Incentive Program and to terminate and modify requirements for the ESRD Treatment Choices Model.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by August 29, 2025.

ADDRESSES: In commenting, please refer to file code CMS-1830-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-1830-P, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1830-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:

ESRDPayment@cms.hhs.gov or Abigail Ryan 410-786-4343 for issues related to the ESRD Prospective Payment System (PPS) and coverage and payment for renal dialysis services furnished to individuals with acute kidney injury (AKI).

ESRDApplications@cms.hhs.gov, for issues related to applications for the Transitional Drug Add-on Payment Adjustment (TDAPA) or Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

ESRDQIP@cms.hhs.gov, for issues related to the ESRD Quality Incentive Program (QIP).

ETC-CMMI@cms.hhs.gov, for issues related to the ESRD Treatment Choices (ETC) Model.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://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 plain language summary of this rule may be found at <https://www.regulations.gov/>.

Current Procedural Terminology (CPT) Copyright Notice: Throughout this proposed rule, we use CPT® codes and descriptions to refer to a variety of services. We note that CPT® codes and descriptions are copyright 2020 American Medical Association (AMA). All Rights Reserved. CPT® is a registered trademark of the AMA. Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

Deregulation Request for Information (RFI):

On January 31, 2025, President Trump issued Executive Order (E.O.) 14192 “Unleashing Prosperity Through Deregulation,” which states the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America’s economic prosperity and national security and the highest possible quality of life for each citizen. We would like public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in the Medicare program. CMS has made available an RFI at <https://www.cms.gov/medicare-regulatory-relief-rfi>. Please submit all comments in response to this RFI through the provided weblink.

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I. Executive Summary

A. Purpose

This rule proposes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model.

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule proposes updates to the ESRD PPS for CY 2026. This rule also proposes to modify the eligibility timeframe for the transitional drug add-on payment adjustment (TDAPA) and to establish a new payment adjustment for ESRD facilities in certain non-contiguous states and territories to promote efficient allocation of payments.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This proposed rule proposes to update the AKI dialysis payment rate for CY 2026.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program establishes incentives for facilities to achieve high quality performance on measures with the goal of improving outcomes for ESRD beneficiaries. Beginning with PY 2027, this proposed rule proposes to remove the Facility Commitment to Health Equity reporting measure, the Screening for Social Drivers of Health reporting measure, and the Screen Positive Rate for Social Drivers of Health reporting measure from the ESRD QIP measure set. In addition, this proposed rule proposes to update the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure beginning with PY 2028. Finally, this proposed rule requests public comment on several topics relevant to the ESRD QIP.

4. End-Stage Renal Disease Treatment Choices (ETC) Model

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center). The ETC Model tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model was finalized as part of

a final rule published in the **Federal Register** on September 29, 2020, titled “Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures” (85 FR 61114), referred to herein as the “Specialty Care Models final rule.” Subsequently, the ETC Model has been updated four times in the annual ESRD PPS final rules for calendar year (CY) 2022 (86 FR 61874), CY 2023 (87 FR 67136), CY 2024 (88 FR 76344), and CY 2025 (89 FR 89084).

Per model evaluation reports, ETC Model performance since 2021 has continued to show that the model is not having a statistically significant impact on the use of home dialysis modalities, transplant waitlisting, and living donor transplantation. In this rule, we are proposing to terminate the ETC Model as of December 31, 2025 and also to modify the duration during which CMS will apply payment adjustments described in 42 CFR part 512, subpart C for a specific time period.

B. Summary of the Major Provisions

1. ESRD PPS

- *Proposed update to the ESRD PPS base rate for CY 2026:* The proposed CY 2026 ESRD PPS base rate is \$281.06, an increase from the CY 2025 ESRD PPS base rate of \$273.82. This proposed amount reflects the application of the wage index budget neutrality adjustment factor (1.00872), the budget neutrality factor for the proposed non-contiguous areas payment adjustment (NAPA) (0.99859) as discussed in section II.B.8. of this proposed rule, and a proposed ESRD Bundled (ESRDB) market basket update of 1.9 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $\$281.06 ((\$273.82 \times 1.00872 \times 0.99859) \times 1.019 = \$281.06)$.

- *Proposed annual update to the wage index:* We adjust the ESRD PPS wage index on an annual basis using the most current mean hourly wage data for occupations related to the furnishing of renal dialysis services from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) program and occupational mix data from the most recent full CY of freestanding ESRD facility Medicare cost reports. This wage index uses the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2026, we are proposing updates to the wage index based on this methodology and the latest available data.

- *Proposed annual update to the outlier policy:* We are proposing to update the outlier policy based on the most current data and established

methodology. Accordingly, we are proposing to update the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2026 using the latest available CY 2024 claims data. We are proposing to update the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2024 claims data and to update the FDL amount for adult patients using the latest available claims data from CY 2022, CY 2023, and CY 2024. For pediatric beneficiaries, the FDL amount would decrease from \$234.26 to \$148.38, and the MAP amount would decrease from \$59.60 to \$44.09, as compared to CY 2025 values. For adult beneficiaries, the FDL amount would decrease from \$45.41 to \$12.74, and the MAP amount would decrease from \$31.02 to \$22.07. The 1.0 percent target for outlier payments was not achieved in CY 2024, as outlier payments represented approximately 0.8 percent of total Medicare payments.

- *Proposed update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2026:* The proposed CY 2026 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is \$10.41. This proposed offset amount reflects the application of the proposed ESRDB market basket update of 1.9 percent ($\$10.22 \times 1.019 = \$10.41$). There are no capital-related assets set to receive the TPNIES in CY 2026 for which this offset would apply.

- *Proposed update to the post-TDAPA add-on payment adjustment amounts:* We calculate the post-TDAPA add-on payment adjustment in accordance with 42 CFR 413.234(g). The proposed post-TDAPA add-on payment adjustment amount for Korsuva® is \$0.2633 per treatment, which would be included in the calculation of the total post-TDAPA add-on payment adjustment for each quarter in CY 2026. The proposed post-TDAPA add-on

payment adjustment amount for DefenCath® is \$1.4780 per treatment, which would be included in the calculation for the third and fourth quarter of CY 2026.

- *Proposed update to the timeframe for TDAPA eligibility:* We are proposing to modify the timeframe for TDAPA eligibility to provide that a new renal dialysis drug or biological product must have been approved by the Food and Drug Administration (FDA) within the past 3 years at the time of submission of the TDAPA application. This would be consistent with the timeframe used for TPNIES eligibility. This proposed eligibility timeframe would apply for all new drugs and biological products for which a TDAPA application is submitted on or after January 1, 2028.

- *Proposed non-contiguous areas payment adjustment (NAPA):* We are proposing a new payment adjustment for ESRD facilities in certain high-cost, non-contiguous states and territories to account for certain non-labor costs which are not captured in the ESRD PPS wage index. As proposed, this payment adjustment would apply to ESRD PPS claims submitted by ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories of Guam, American Samoa, and the Northern Mariana Islands. We are also proposing that the NAPA would be budget neutral and a corresponding budget neutrality factor of 0.99859 would be applied to the CY 2026 ESRD PPS base rate.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

- *Proposed update to the dialysis payment rate for individuals with AKI:* We are proposing an update to the AKI dialysis payment rate for CY 2026. The proposed CY 2026 payment rate is \$281.06, which is the same as the proposed CY 2026 ESRD PPS base rate.

3. ESRD QIP

We are proposing to remove the Facility Commitment to Health Equity reporting measure beginning with PY

2027, the Screening for Social Drivers of Health reporting measure beginning with PY 2027, and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027. Beginning with PY 2028, we are proposing to update the ICH CAHPS clinical measure. We are proposing to reduce the length of the ICH CAHPS Survey by removing 23 questions which we have identified as appropriate for removal. We are also including requests for information (RFIs) on several topics relevant to the ESRD QIP. We are requesting information on the current state of health information technology (IT) use in dialysis facilities, including electronic health records, to further ongoing CMS efforts to facilitate successful adoption and integration of Fast Healthcare Interoperability Resources® (FHIR®) and FHIR-based technologies and standardized data for patient assessment instruments. We are also requesting feedback on potential measurement concepts that could be developed into ESRD QIP measures in the future, such as measures of interoperability, well-being, nutrition, and physical activity.

4. ETC Model

We are proposing to terminate the ETC Model and modify the duration during which CMS would apply the payment adjustments described in 42 CFR part 512, subpart C to claims with claim service dates beginning on or after January 1, 2021, and ending on or before December 31, 2025. We discuss our reasons for proposing to terminate the model and the changes to the regulation required to implement the proposed termination.

C. Summary of Costs and Benefits

In section VIII.C.5. of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. Table 1 summarizes the impacts of each proposed provision in this CY 2026 ESRD PPS proposed rule.

TABLE 1—ESTIMATED TOTAL COSTS/TRANSFERS

Proposals	Estimated total costs/transfers
Proposed CY 2026 ESRD PPS updates.	The overall economic impact of this proposed rule is an estimated increase of approximately \$160 million in aggregate payments to ESRD facilities in CY 2026. This includes estimated expenditures of approximately \$27 million associated with the post-TDAPA add-on payment adjustment.
Proposed CY 2026 AKI dialysis payment rate update.	We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the proposed CY 2026 ESRD PPS base rate, would increase by \$1 million.
Proposed PY 2027 and PY 2028 QIP updates.	We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are proposing, the overall economic impact of the PY 2027 ESRD QIP would be approximately \$146.8 million. We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are proposing, the overall economic impact of the PY 2028 ESRD QIP would be approximately \$143.1 million.
Proposed ETC Model termination.	We estimate that, as a result of the termination of the ETC Model, as proposed in this rule, the net Federal impact would be approximately \$1 million in savings.

1. Impacts of the Proposed Updates to the ESRD PPS

The impact table in section VIII.C.5.a. of this proposed rule displays the estimated change in Medicare payments to ESRD facilities in CY 2026 compared to estimated Medicare payments in CY 2025. The overall impact of the proposed CY 2026 payment changes, if finalized, is projected to be a 1.9 percent increase in Medicare payments. Hospital-based ESRD facilities would have an estimated 1.5 percent increase in Medicare payments compared with freestanding ESRD facilities with an estimated 1.9 percent increase. We estimate that the aggregate Medicare payments under the ESRD PPS would increase by approximately \$160 million in CY 2026 compared to CY 2025 as a result of the proposed payment policies in this rule. Because of the projected 1.9 percent overall payment increase, we estimate there would be an increase in beneficiary coinsurance payments of 1.9 percent in CY 2026, which translates to approximately \$30 million. For CY 2026, we estimate total payments associated with the post-TDAPA add-on payment adjustment would be \$27.6 million.

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Under this authority, CMS implemented § 413.234 to establish the TDAPA, a transitional drug add-on payment adjustment for certain new renal dialysis drugs and biological products, § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for certain new and innovative equipment and supplies, and § 413.234(g) to establish the post-TDAPA add-on payment adjustment. The TDAPA, the TPNIES, and the post-TDAPA add-on payment adjustment are not budget neutral.

As discussed in section II.D. of this proposed rule, because we did not receive any applications for the TPNIES in CY 2025, no new items were approved for the TPNIES for CY 2025 (89 FR 89162). Therefore, there are no continuing TPNIES payments for CY 2026. In addition, since we did not receive any applications for the TPNIES for CY 2026, there will be no new TPNIES payments for CY 2026. As discussed in section II.E. of this proposed rule, the TDAPA payment periods for DefenCath®, Vaseo®, and the oral-only phosphate binders sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate will

continue into CY 2026. As described in section VIII.C.5.b. of this proposed rule, we estimate that the combined total TDAPA payment amounts for these drugs in CY 2026 would be approximately \$480 million, of which, \$100 million would be attributed to beneficiary coinsurance amounts.

2. Impacts of the Proposed Payment Rate for Renal Dialysis Services Furnished to Individuals With AKI

The impact table in section VIII.C.5.c. of this proposed rule displays the estimated change in Medicare payments to ESRD facilities for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for such services in CY 2025. The overall impact of the proposed CY 2026 changes is projected to be a 1.8 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities would have an estimated 1.6 percent increase in Medicare payments compared with freestanding ESRD facilities that would have an estimated 1.8 percent increase. The overall impact reflects the effects of the proposed Medicare ESRD PPS payment rate update and the proposed CY 2026 ESRD PPS wage index. We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the proposed CY 2026 ESRD PPS base rate, would increase by \$1 million in CY 2026 compared to CY 2025.

3. Impacts of the PY 2027 and PY 2028 ESRD QIP

We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are proposing, the overall economic impact of the PY 2027 ESRD QIP would be approximately \$146.8 million. The \$146.8 million estimate for PY 2027 includes \$124.7 million in costs associated with the collection of information requirements and approximately \$22.1 million in payment reductions across all facilities. We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are proposing, the overall economic impact of the PY 2028 ESRD QIP would be approximately \$143.1 million. The \$143.1 million estimate for PY 2028 includes \$124.7 million in costs associated with the collection of information requirements and approximately \$18.4 million in payment reductions across all facilities.

4. Impacts of the Proposed Termination of the ETC Model

We estimate that, as a result of the termination of the ETC Model, as proposed in this rule, the net Federal impact would be approximately \$1 million in savings.

II. Calendar Year (CY) 2026 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148), established that beginning with CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014, to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals¹ (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule, we finalized \$29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. Section 632(c) of ATRA required

¹ As discussed in the CY 2019 ESRD PPS final rule (83 FR 56922), we began using the term “biological products” instead of “biologicals” under the ESRD PPS to be consistent with FDA nomenclature. We use the term “biological products” in this proposed rule except when referencing specific language in the Act or regulations.

the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket percentage increase should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025. Effective January 1, 2025, all oral-only renal dialysis drugs and biological products are paid for under the ESRD PPS.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to an individual for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies.

The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 13, or age 13 to 17) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)(1)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments, with two tiers such that smaller low volume facilities receive a higher payment adjustment (§ 413.232). The second payment adjustment reflects differences in area wage levels developed from core-based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

There are six additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); (4) a TPNIES for certain new and innovative renal dialysis equipment and supplies (§ 413.236(d)); (5) a transitional pediatric ESRD add-on payment adjustment (TPEAPA) of 30 percent of the per-treatment payment amount for renal dialysis services furnished to pediatric ESRD patients for CYs 2024 through 2026 (§ 413.235(b)(2)); and (6) a post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA period (§ 413.234(g)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule appeared in the August 12, 2010, issue of the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added

by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

Most recently, we published a final rule, which appeared in the November 12, 2024, issue of the **Federal Register**, titled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model,” referred to herein as the “CY 2025 ESRD PPS final rule.” In that rule (89 FR 89084 through 89213), we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2025 and we updated the CBSA delineations used for the wage index according to Office of Management and Budget (OMB) Bulletin No. 23–01. We also finalized a new ESRD PPS wage index methodology, a phase out of the rural adjustment for ESRD facilities that were re-designated from a rural to an urban area as a result of the new CBSA delineations, an expansion of the ESRD PPS outlier list to include all drugs and biological products that were formerly part of the composite rate, an updated methodology for calculating certain inflation factors used when determining the adult fixed dollar loss (FDL) amount, and an update to the low-volume payment adjustment (LVPA) to include two tiers such that ESRD facilities with fewer than 3000 treatments in 2 of the 3 preceding years would receive a higher LVPA payment. Additionally, in the CY 2025 ESRD PPS final rule, we discussed the inclusion of oral-only drugs into the ESRD PPS bundled payment and finalized monthly TDAPA amounts for claims which utilize phosphate binders. For further detailed information regarding these updates and policy changes, see 89 FR 89084.

B. Proposed Provisions of the CY 2026 ESRD PPS

1. Proposed CY 2026 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share

a. Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase and reduced

by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. Section 1881(b)(14)(F)(i) of the Act also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD bundled (ESRDB) input price index using CY 2008 as the base year (75 FR 49151 through 49162). We subsequently revised and rebased the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). In the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964), we finalized a rebased ESRDB input price index to reflect a CY 2016 base year. In the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), we finalized a revised and rebased ESRDB input price index to reflect a CY 2020 base year.

Although “market basket” technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term “ESRDB market basket”, as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

b. Proposed CY 2026 ESRD Market Basket Update

We are proposing to use the 2020-based ESRDB market basket as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154) to compute the CY 2026 ESRDB market basket percentage increase based on the best available data. Consistent with historical practice, we propose to estimate the ESRDB market basket percentage increase based on IHS Global Inc.’s (IGI) forecast using the most recently available data at the time of rulemaking. IGI is a nationally recognized economic and financial

forecasting firm with which CMS contracts to forecast the components of the market baskets. As discussed in section II.B.1.b.(3). of this proposed rule, we are calculating the proposed ESRDB market basket update for CY 2026 based on the proposed ESRDB market basket percentage increase and the proposed productivity adjustment, following our longstanding methodology.

(1) Proposed CY 2026 ESRDB Market Basket Percentage Increase

Based on IGI’s first quarter 2025 forecast of the 2020-based ESRDB market basket, the proposed CY 2026 ESRDB market basket percentage increase is 2.7 percent. We are proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase), we would use such data, if appropriate, to determine the CY 2026 ESRDB market basket percentage increase in the final rule.

(2) Proposed CY 2026 Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRDB market basket percentage increase shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year (FY), year, cost reporting period, or other annual period), hereafter referred to as the “productivity adjustment”.

The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. As we noted in the CY 2023 ESRD PPS final rule (87 FR 67155), the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act previously was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term “multifactor productivity” with “total factor productivity” (TFP). BLS noted that this is a change in terminology only and would not affect the data or

methodology.² As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP; however, as mentioned previously, the data and methods are unchanged. We refer readers to <https://www.bls.gov/productivity/> for the BLS historical published TFP data. A complete description of IGI’s TFP projection methodology is available on CMS’s website at <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information>. In addition, in the CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, we would be changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment.

Based on IGI’s first quarter 2025 forecast, the proposed productivity adjustment for CY 2026 (the 10-year moving average growth of TFP for the period ending CY 2026) is 0.8 percentage point. Furthermore, we are proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the CY 2026 productivity adjustment in the final rule.

(3) Proposed CY 2026 ESRDB Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we are proposing to base the CY 2026 ESRDB market basket percentage increase on IGI’s first quarter 2025 forecast of the 2020-based ESRDB market basket. We propose to then reduce the ESRDB market basket percentage increase by the proposed productivity adjustment for CY 2026 based on IGI’s first quarter 2025 forecast. Therefore, the proposed CY 2026 ESRDB market basket update is equal to 1.9 percent (proposed 2.7 percent ESRDB market basket percentage increase reduced by a proposed 0.8 percentage point productivity adjustment). Furthermore, as noted previously, we are proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase or

² Total Factor Productivity in Major Industries—2020. Available at <https://www.bls.gov/news.release/prod5.nr0.htm>.

productivity adjustment), we would use such data, if appropriate, to determine the CY 2026 ESRD market basket percentage increase and productivity adjustment in the final rule.

(4) Proposed ESRD Labor-Related Share

We define the labor-related share as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. For the CY 2026 ESRD PPS payment update, we are proposing to continue using a labor-related share of 55.2 percent, which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154).

2. Proposed CY 2026 ESRD PPS Wage Indices

a. Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, we established a policy to adjust the labor-related portion of the ESRD PPS base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. As discussed in detail later in this section, we later implemented an ESRD PPS specific wage index methodology in the CY 2025 ESRD PPS final rule (89 FR 89108 through 89117). Under current policy, we use OMB's CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. We most recently updated the CBSA delineations in the CY 2025 ESRD PPS final rule (89 FR 89117) to the OMB delineations as described in OMB Bulletin No. 23–01, beginning with the CY 2025 ESRD PPS wage index.³

Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). Currently, all areas with wage index values that fall below the floor are located in Puerto Rico and the U.S. Virgin Islands. However, the wage index floor value is applicable for any area that may fall below the floor. A further description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967) and the CY 2023 ESRD PPS final rule (87 FR 67161).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2023 ESRD PPS final rule (87 FR 67153), we finalized the use of a labor-related share of 55.2 percent. In the CY 2021 ESRD PPS final rule (85 FR 71436), we finalized a temporary policy which applied a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. In the CY 2023 ESRD PPS final rule (87 FR 67161), we finalized a permanent policy under § 413.231(c) to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. For CY 2026, as discussed in section II.B.1.b.(4). of this proposed rule, we are proposing that the labor-related share to which the wage index would be applied is 55.2 percent.

In the CY 2011 ESRD PPS final rule (75 FR 49116) and the CY 2011 final rule on Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B (75 FR 73486) we established an ESRD PPS wage index methodology to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the hospital inpatient prospective payment system (IPPS). The ESRD PPS wage index values have historically been calculated without regard to geographic reclassifications authorized for acute care hospitals under sections 1886(d)(8) and (d)(10) of the Act and utilized pre-floor hospital data that are unadjusted

for occupational mix. In the CY 2025 ESRD PPS final rule (89 FR 89116) we finalized a new ESRD PPS wage index methodology which uses mean hourly wage data from the Bureau of Labor Statistics (BLS) Occupational Employment Wages & Statistics (OEWS). This wage data is then weighted by a national ESRD facility occupational mix (NEFOM) which is derived from full time equivalent (FTE) data from freestanding ESRD facility cost report data. Treatment data from ESRD facility cost reports is also used to weigh the mean hourly wage data when aggregating the wage data at a CBSA level. As set forth in 42 CFR 413.196(d)(2), we update the ESRD PPS wage index using the most current wage data for occupations related to the furnishing of renal dialysis services from BLS and occupational mix data from the most recent full CY of Medicare cost reports submitted in accordance with § 413.198(b).

For a detailed explanation of the current ESRD PPS wage index methodology, see the discussion in the CY 2025 ESRD PPS final rule (89 FR 89108 through 89117), and for a detailed explanation of the steps we use to calculate the ESRD PPS wage index according to this methodology see Addendum C on the CY 2025 ESRD PPS proposed rule available here: <https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-payment-regulations-and-notice/cms-1805-p>.

b. National ESRD Facility Occupational Mix

Table 2 presents the national ESRD facility occupational mix (NEFOM) alongside the BLS occupation titles and codes for the occupations related to the furnishing of renal dialysis services. We note that we are presenting the NEFOM in this CY 2026 ESRD PPS proposed rule to aid interested parties in their reconstruction of the proposed ESRD PPS wage index, but the actual ESRD PPS wage index uses the total FTEs for each occupation as described in the calculation in Addendum C of the CY 2025 ESRD PPS proposed rule rather than the rounded percentages presented in Table 2. This table is based on data from CY 2023 freestanding ESRD facility cost reports, although we note that the NEFOM has not changed significantly from the NEFOM presented in the CY 2025 ESRD PPS final rule (89 FR 89101).

³ <https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf>.

TABLE 2—CROSSWALK OF BLS OCCUPATION CODES TO ESRD FACILITY COST REPORTS OCCUPATION CLASSIFICATIONS AND THE CY 2026 ESRD PPS PROPOSED RULE NEFOM

ESRD PPS colloquial name	BLS occupation title	Occupation code	ESRD free-standing facilities FTE percentage (rounded)
Registered Nurses (RN)	Registered Nurses	29–1141	30.0
Licensed Practical Nurses (LPN)	Licensed Practical and Licensed Vocational Nurses	29–2061	4.0
Nurse Aides	Nursing Assistants	31–1131	2.4
Technicians	Health Technologists and Technicians, All Other	29–2099	38.1
Social Workers	Healthcare Social Workers	21–1022	4.7
Dietitians	Dietitians and Nutritionists	29–1031	4.5
Administrative Staff	Medical Secretaries and Administrative Assistants ..	43–6013	10.7
Management	Medical and Health Services Managers	11–9111	5.5

c. Missing May 2024 BLS OEWS Data for Colorado

BLS reported data quality concerns for the May 2024 BLS OEWS estimates for Colorado and did not include any areas of Colorado in this release.⁴ Per § 413.196(d)(2) we use the most current BLS wage data for the occupations related to the furnishing of renal dialysis services for our ESRD PPS wage index. In the CY 2025 ESRD PPS final rule, we discussed a methodology for imputing missing data using regression based on the most similar occupation to the occupation for which there was missing data (89 FR 89100). We believe that this methodology is generally most appropriate as it uses current OEWS data to impute the missing estimates; however, that methodology would not be as useful in this situation since the mean hourly wage estimates for all occupations are missing for all 7 CBSAs and one rural area in Colorado. In this instance we do not believe there is sufficient May 2024 OEWS data from which to impute the missing values. To address this missing data, we are proposing to instead use the May 2023 BLS OEWS means hourly wage estimates for the occupations in question and adjust them to be comparable with 2024 wage values by multiplying the wage estimates by an adjustment factor based on the average change in national BLS OEWS wages for each occupation in the NEFOM. The adjustment factors we have applied in our proposed CY 2026 ESRD PPS wage index are the percent change of national average wage for the occupation in

question for 2024 compared to the national average wage for that occupation for 2023 from the May 2024 and May 2023 OEWS, respectively. This adjustment is necessary since the wage index is relative and if wages are higher in 2024 relative to 2023, using the unadjusted 2023 values might result in an inappropriately low wage index value for Colorado. Alternatively, we could freeze the CY 2023 wage index values for Colorado, which would accomplish a similar purpose, but we believe that our proposed methodology is most consistent with the language at § 413.196(d)(2) as we are using the most current mean hourly wage data from the BLS OEWS for Colorado, which is from the May 2023 OEWS. Should BLS release the May 2024 OEWS estimates for Colorado before the publication of the ESRD PPS final rule, we propose to use those estimates instead of the adjusted May 2023 OEWS estimates for the final CY 2026 ESRD PPS wage index. We request comments on this proposed methodology to address missing Colorado OEWS data.

d. Proposed CY 2026 ESRD PPS Wage Index

For CY 2026, we are proposing to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using the ESRD PPS wage index methodology established in the CY 2025 ESRD PPS final rule (89 FR 89098 through 89107) and specified in § 413.196(d)(2). We are proposing to use the most recent available BLS OEWS mean hourly wage data for various occupations related to the furnishing of renal dialysis services weighted by FTE data from CY 2023 freestanding ESRD facility cost reports. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act. For CY 2026, the updated wage data used in the analysis for this

proposed rule are from the April 2025 release of the BLS OEWS, which represents data from six semiannual surveys spanning November 2021 through May 2024.⁵

For CY 2026, we propose to update the ESRD PPS wage index to use the most recent available BLS OEWS wage data. We are proposing that if more recent data become available after the analysis performed for the publication of this proposed rule and before the publication of the final rule (for example, an update to the May 2024 BLS OEWS mean hourly wage data or more complete CY 2023 cost report data), we would use such data, if appropriate, to determine the CY 2026 ESRD PPS wage index in the final rule. The proposed CY 2026 ESRD PPS wage index is set forth in Addendum A and provides a crosswalk between the CY 2025 wage index and the proposed CY 2026 wage index. Addendum B provides an ESRD facility level impact analysis. Both Addendum A and Addendum B are available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>.

3. Proposed CY 2026 Update to the Outlier Policy

a. Background

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high-cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care are frailty and obesity. A

⁵ <https://www.bls.gov/news.release/pdf/ocwage.pdf>.

⁴ All wage data for Colorado is missing in the 2024 OEWS release due to concerns related to the quality of the data. According to BLS, this concern was not with the OEWS survey results, but rather with employment data from the Quarterly Census of Employment and Wages (QCEW). OEWS uses QCEW employment data to adjust estimates to represent all employment that is in scope for the OEWS survey. For more information, see <https://www.bls.gov/oes/notices/2024/colorado-data.htm>.

patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes that some patients require high-cost care, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

Section 413.237(a)(1) enumerates the following items and services that are eligible for outlier payments as ESRD outlier services:

- Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.
- Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.
- Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.
- Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025.
- Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.⁶
- Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the ESRD facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as ESRD outlier services were specified in Transmittal 2134, dated January 14, 2011.⁷ We use

administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests (CRs), when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based on our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. In past years, the MAP amount has reflected the average estimated expenditure per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted MAP per treatment plus the fixed dollar loss (FDL) amount. As described in the following paragraphs, the ESRD facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term "national adjusted average" in this section of this proposed rule to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage—which is used to reduce the per treatment ESRD PPS base rate to account for the proportion of the estimated total Medicare payments under the ESRD PPS that are outlier

payments—at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments.

In the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177). We explained that for several years, outlier payments had consistently landed below the target of 1.0 percent of total ESRD PPS payments (87 FR 67169). Commenters raised concerns that the methodology we used to calculate the outlier payment adjustment since CY 2011 results in underpayment to ESRD facilities, as the base rate has been reduced by 1.0 percent since the establishment of the ESRD PPS to balance the outlier payment (85 FR 71409, 71438 through 71439; 84 FR 60705 through 60706; 83 FR 56969). In response to these concerns, beginning with CY 2023, we began calculating the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. We stated in the CY 2023 ESRD PPS final rule that we would continue to calculate the adult and pediatric MAP amounts for CY2023 and subsequent years following our established methodology. In that same CY 2023 ESRD PPS final rule, we provided a detailed discussion of the methodology we use to calculate the MAP amounts and FDL amounts (87 FR 67167 through 67169).

Lastly, in the CY 2025 ESRD PPS final rule we finalized several methodological and policy changes to the ESRD PPS outlier policy to address concerns that interested parties have raised in recent years. First, we finalized an expansion of the definition of ESRD outlier services in § 413.237(a)(1) to include drugs and biological products that are Composite Rate Services as defined in § 413.171 (89 FR 89126). Second, we finalized a policy to include the case-

⁶ Under § 413.237(a)(1)(vi), as of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

⁷ Transmittal 2033 issued August 20, 2010, was rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD PPS outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf>.

mix adjusted post-TDAPA add-on payment adjustment amount in the calculation of the MAP amounts when applicable (89 FR 89127). Lastly, we finalized changes to the inflation factors for outlier eligible drugs and biological products, laboratory tests, and supplies. For ESRD outlier drugs and biological products, we use the projected inflation factor for ESRD outlier services that are drugs and biological products derived from the historical trend in average sales price (ASP) prices and utilization for ESRD outlier drugs (89 FR 89127 through 89130). For ESRD outlier laboratory tests and supplies, we use the growth in the producer price index (PPI) Industry for Medical and Diagnostic Laboratories and the PPI Commodity for Surgical and Medical Instruments,

respectively (89 FR 89129 through 89130).

b. Proposed CY 2026 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2026, we are proposing to update the MAP amounts for adult and pediatric patients using the latest available CY 2024 claims data. We are proposing to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2024 claims data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2022, CY 2023, and CY 2024, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174) and including the

changes finalized in the CY 2025 ESRD PPS final rule (89 FR 89108 through 89130). The latest available CY 2024 claims data show that outlier payments represented approximately 0.8 percent of total Medicare payments. We are proposing to update these values with the latest available data, if appropriate, in the final rule.

The impact of this proposed update is shown in Table 3, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2025 with the updated estimates for this proposed rule for CY 2026. The estimates for the proposed CY 2026 MAP amounts, as shown in column II of Table 3, were inflation adjusted to reflect projected 2026 prices for ESRD outlier services.

TABLE 3—PROPOSED OUTLIER POLICY: IMPACT OF UPDATED DATA FOR THE OUTLIER POLICY

	Column I Final outlier policy for CY 2025 (based on 2023 data, price inflated to 2025)*		Column II Proposed outlier policy for CY 2026 (based on 2024 data, price inflated to 2026)**	
	Age <18	Age ≥18	Age <18	Age ≥18
Average outlier services MAP amount per treatment	\$58.30	\$32.40	\$43.92	\$23.11
Adjustments:				
Standardization for outlier services	1.0432	0.9768	1.0244	0.9745
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	\$59.60	\$31.02	\$44.09	\$22.07
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	\$234.26	\$45.41	\$148.38	\$12.74
Patient-month-facilities qualifying for outlier payment	6.09%	7.05%	7.05%	14.16%

* Column I was obtained from column II of Table 7 from the CY 2025 ESRD PPS final rule (89 FR 89130).

** The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2022, 2023, and 2024.

As demonstrated in Table 3, the proposed FDL amount per treatment amount that determines the CY 2026 outlier threshold amount for adults (column II; \$12.74) is lower than that used for the CY 2025 outlier policy (column I; \$45.41). The lower threshold amount is accompanied by a decrease in the adjusted average MAP for outlier services from \$31.02 to \$22.07. For pediatric patients, there is a decrease in the FDL amount from \$234.26 to \$148.38. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from \$59.60 to \$44.09. We note that the decrease in the projected MAP and FDL amounts for both adult and pediatric patients is due, in part, to the application of the ESRD PPS drug inflation factor following the methodology finalized in the CY 2025 ESRD PPS final rule (89 FR 89127 through 89130), which resulted in a lower inflation factor than would typically occur under the prior methodology. However, as discussed in that rule, we believe this methodology is more appropriate for the ESRD PPS as it more accurately captures trends in the

prices and utilization of ESRD PPS outlier services drugs and biological products.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2026 would be 14.16 percent for adult patients and 7.05 percent for pediatric patients, based on the 2024 claims data.

c. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1.0 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. In the 2023 ESRD PPS final rule, we finalized a change to the outlier methodology to better achieve this 1.0 percent target (87 FR 67170 through 67174). Based on the preliminary CY 2024 claims, outlier payments represented approximately 0.8 percent of total payments, which is slightly below the 1.0 percent target.

4. Proposed Impacts to the CY 2026 ESRD PPS Base Rate

a. Proposed ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, the ESRD PPS base rate, and calculating the per-treatment payment amount, which are codified at §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our

regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, the TDAPA, the TPNIES, the post-TDAPA add-on payment adjustment, and the TPEAPA for CYs 2024, 2025 and 2026.

b. Proposed Annual Payment Rate Update for CY 2026

We are proposing an ESRD PPS base rate for CY 2026 of \$281.06. This would be approximately a 2.6 percent increase from the CY 2025 ESRD PPS base rate of \$273.82. This proposed update reflects several factors, described in more detail as follows:

Wage Index Budget Neutrality Adjustment Factor: We compute a wage index budget neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2026, we are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 2026 wage index budget neutrality adjustment factor using treatment counts from the 2024 claims and facility-specific CY 2025 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2025. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2026. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the proposed CY 2026 ESRD PPS wage index and proposed labor-related share for CY 2026. The total of these payments becomes the new CY 2026 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget neutrality factor is calculated as the target amount divided by the new CY 2026 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2026 estimated payments, aggregate Medicare payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget neutrality adjustment factor ensures that the wage index updates and revisions do not increase or decrease aggregate Medicare payments. The proposed CY 2026 wage index budget neutrality adjustment factor is 1.00872. As we are not proposing any changes to our established ESRD PPS wage index policy, this proposed CY 2026 wage

index budget neutrality adjustment factor reflects the impact of all established wage index policies, including the ESRD PPS wage index methodology based on BLS OEWS and freestanding ESRD facility cost report FTE data, the 5 percent cap on year-to-year decreases in wage index values, the 3-year rural phase-out for ESRD facilities in currently-rural CBSAs that became urban under the new delineations adopted in CY 2025, and the labor-related share. We discussed in the CY 2025 ESRD PPS final rule (89 FR 89131) that the impact of the application of the 5 percent cap on wage index decreases had a sizable impact on the budget neutrality factor for CY 2025 due to the new wage index methodology implemented in that year. That is, because a substantial number of ESRD facilities would have experienced a greater than 5 percent decrease in their wage index value as a result of the new wage index methodology, the budget neutrality adjustment factor needed to offset the effect of limiting those decreases to 5 percent had a larger magnitude impact on the ESRD PPS base rate than we expect it would be in a typical year. However, for CY 2026 the continued application of our established 5 percent cap policy would result in a proposed wage-index budget neutrality factor above 1, meaning the proposed ESRD PPS base rate would increase as a result of its application. This is because the average wage index value is decreasing as, generally, ESRD facilities that received the 5 percent cap in CY 2025 are set to receive a lower wage index for CY 2026. We note that the proposed CY 2026 wage index budget neutrality factor does not include any impacts associated with the TPEAPA, as was the case with the 2024's combined wage index-TPEAPA budget neutrality finalized factor for CY 2024. This is consistent with how we have historically applied budget neutrality for case-mix adjusters, including pediatric case-mix adjusters. We do not routinely apply a budget neutrality factor to account for changes in overall payment associated with changes in patient case-mix in years in which we do not propose any changes to the case-mix adjustment amount. Although the TPEAPA was established under the authority in section 1881(b)(14)(D)(iv) of the Act, which does not require budget neutrality, we stated in the CY 2024 ESRD PPS final rule that we were implementing the TPEAPA in a budget neutral manner because it was similar to the pediatric case-mix adjusters, and it accounts for costs which would have been included in the cost reports used

in the analysis conducted when we created the ESRD PPS bundled payment in the CY 2011 ESRD PPS final rule (88 FR 76378). Because the adjustment to maintain budget neutrality associated with the TPEAPA was accounted for in the CY 2024 combined wage index and TPEAPA budget neutrality factor, and we are not proposing any changes to the TPEAPA amount, it would not be appropriate to apply a budget neutrality factor for the TPEAPA for CY 2026.

Proposed NAPA Budget Neutrality Factor: As discussed in section II.B.8. of this proposed rule, under the authority granted by section 1881(b)(14)(D)(iv) of the Act, we are proposing a new facility-level payment adjustment for ESRD facilities in Alaska, Hawaii, and certain U.S. Pacific Territories,⁸ which we refer to in this proposed rule as the proposed non-contiguous areas payment adjustment (NAPA). As proposed, this payment adjustment would apply to ESRD PPS claims for treatments at ESRD facilities in Alaska, Hawaii, Guam, American Samoa, and the Northern Mariana Islands. This payment adjustment would be capped at 25 percent and would be applied to the non-labor-related share of the ESRD PPS base rate, which is 44.8 percent. We are proposing that this payment adjustment would be budget neutral and would result in a proposed NAPA budget neutrality factor of 0.99859.

Proposed Market Basket Update: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase. As discussed in section II.B.1.b.(1). of this proposed rule, the latest CY 2026 projection of the ESRDB market basket percentage increase is 2.7 percent. In CY 2026, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As previously discussed in section II.B.1.b.(2). of this proposed rule, the latest CY 2026 projection of the productivity adjustment is 0.8 percentage point, thus yielding a proposed CY 2026 ESRDB market basket update of 1.9 percent for CY 2026. Therefore, the proposed CY 2026 ESRD PPS base rate is \$281.06 $(\$273.82 \times 1.00872 \times 0.99859) \times 1.019 = \$281.06$). As discussed in section II.B.1.b. of this proposed rule, we are proposing that if more recent data become available after the publication of this proposed rule

⁸ See section II.B.8.b of this proposed rule for a discussion of which U.S. Pacific Territories we considered for this proposal.

and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2026 ESRDB market basket update in the final rule.

We invite public comment on our proposed CY 2026 ESRD PPS base rate.

5. Proposed Update to the Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the TPNIES basis of payment for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. For purposes of this proposed rule, we refer to this as the "TPNIES offset amount."

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRDB market basket update. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for 2 CYs.

There are currently no capital-related assets that are home dialysis machines set to receive TPNIES for CY 2026, as the TPNIES payment period for the Tablo® System ended on December 31, 2023, and there are no TPNIES applications for CY 2026. However, as required by § 413.236(f)(3)(v), we are proposing to update the TPNIES offset amount annually according to the methodology described previously.

We are proposing a CY 2026 TPNIES offset amount for capital-related assets that are home dialysis machines of \$10.41, based on the proposed CY 2026 ESRDB market basket update of 1.9 percent (proposed 2.7 percent ESRDB market basket percentage increase reduced by the proposed 0.8 percentage

point productivity adjustment). Applying the proposed ESRDB market basket update factor of 1.019 to the CY 2025 offset amount results in the proposed CY 2026 offset amount of \$10.41 ($\$10.22 \times 1.019 = \$10.41$). We request public comments on our proposal to update the TPNIES offset for capital-related assets for CY 2026.

6. Proposed Post-TDAPA Add-On Payment Adjustment Updates

In the CY 2024 ESRD PPS final rule we finalized an add-on payment adjustment for certain new renal dialysis drugs and biological products, which would be applied for 3 years after the end of the TDAPA period (88 FR 76388 through 76397). This adjustment, known as the post-TDAPA add-on payment adjustment, is adjusted by the patient-level case-mix adjusters and is applied to every ESRD PPS claim. In that final rule we also clarified that for each year of the post-TDAPA period we would update the post-TDAPA add-on payment adjustment amounts based on utilization and ASP of the drug or biological product. The post-TDAPA add-on payment amounts are calculated based on the methodology codified at § 413.234(g), which is the total drug expenditure divided by the total ESRD PPS treatments multiplied by the case mix standardization for the time period and the 0.65 risk sharing factor, and the ESRDB pharmaceutical price proxy for the payment year (88 FR 76396). In the CY 2025 ESRD PPS final rule (89 FR 89136) we finalized our proposal to publish the post-TDAPA add-on payment adjustment amount after the final rule in certain circumstances to ensure that the post-TDAPA add-on payment adjustment amount can be calculated using 12 months of utilization data.

For CY 2025 there is one drug, Korsuva® (difelikefalin), included in the calculation of the post-TDAPA add-on payment adjustment for each of the four calendar quarters and one drug, Jesdubroq®, included in the calculation for only the fourth calendar quarter. In the CY 2025 ESRD PPS final rule (89 FR 89135), we finalized that the post-TDAPA add-on payment adjustment amount for Korsuva® would be \$0.4601 for CY 2025; this figure was updated to \$0.4684 in transmittal 13245, which was a correction to CR 13865 after a review found a small error in the calculation of this figure. At the time of rulemaking, we did not have sufficient data to finalize a post-TDAPA add-on payment adjustment amount for Jesdubroq® for CY 2025, so, consistent with our policy finalized in the CY 2025 ESRD PPS final rule (89 FR 89136), we published the

final post-TDAPA amount for Jesdubroq® in transmittal 13245.

a. CY 2026 Post-TDAPA Add-On Payment Adjustment Amounts

For CY 2026, we will have three drugs which are in the 3-year period following the end of their TDAPA period and are potentially eligible to be included in the calculation of the post-TDAPA add-on payment adjustment. 42 CFR 413.234(c)(3) states that should CMS not receive the latest full calendar quarter of ASP data for a drug or biological product during the TDAPA or post-TDAPA period, we will not pay any post-TDAPA add-on payment adjustment for such product in any future year. The third quarter of 2025 reflecting quarter 1, 2025 sales would be the latest quarter of ASP data at the time of rulemaking for this proposed rule. As CMS has not received ASP data for quarter 3, 2025, which reflects sales for quarter 1, 2025 for Jesdubroq®, we are not proposing to include Jesdubroq® in the calculation of the post-TDAPA add-on payment adjustment for CY 2026 or any future years. Therefore, conditional upon the continued receipt of the latest full calendar quarter of ASP data for the renal dialysis drugs discussed later in this document, we are anticipating that there would be two drugs included in the calculation of the post-TDAPA add-on payment adjustment for CY 2026.

The post-TDAPA add-on payment adjustment period for one of these drugs, Korsuva®, began on April 1, 2024, so, conditional upon the continued receipt of the latest full calendar quarter of ASP data as described in § 413.234(c)(3), Korsuva® will be included in the calculation for the post-TDAPA add-on payment adjustment for the entirety of CY 2026. The other drug, DefenCath®, began its TDAPA period on July 1, 2024, so it will be included in the post-TDAPA add-on payment adjustment calculation for quarters 3 and 4 of CY 2026, conditional upon the continued receipt of the latest full calendar quarter of ASP data.

For this proposed rule we are presenting the proposed post-TDAPA add-on payment adjustment amounts for Korsuva® based on the most recently available full year of utilization data at this time. We are unable to present an estimate of the post-TDAPA add-on payment adjustment amount for DefenCath® at this time using a full year of utilization data, however we have included a proposed post-TDAPA amount based on the first 6 months of DefenCath® utilization. Consistent with the methodology finalized in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389), we are proposing to

update these calculations with the most recent available utilization and pricing data in the final rule. Table 4 shows the proposed post-TDAPA add-on payment adjustment amounts for each quarter of CY 2026. The proposed post-TDAPA add-on payment adjustment amount for

Korsuva® is \$0.2633 and the proposed post-TDAPA add-on payment adjustment amount for DefenCath® is \$1.4780. At the time of the development of this proposed rule we do not anticipate that there will be any drugs or biological products which would be

included in the post-TDAPA add-on payment adjustment calculation for any quarter of CY 2026 which would lack 12 months of utilization data at the time of final rulemaking.

TABLE 4—PROPOSED POST-TDAPA ADD-ON PAYMENT ADJUSTMENT AMOUNTS FOR CY 2026 BY QUARTER

Quarter	Proposed add-on amount for Korsuva®	Proposed add-on amount for DefenCath® *	Total proposed post-TDAPA add-on payment adjustment amount
Q1 (January–March)	\$0.2633	\$0	\$0.2633
Q2 (April–June)	0.2633	0	0.2633
Q3 (July–September)	0.2633	1.4780	1.7413
Q4 (October–December)	0.2633	1.4780	1.7413

* This figure does not reflect a full year’s utilization data; however, we anticipate that by the time of the publication of the final rule we will have a full year’s utilization data for DefenCath®.

We note that changes in post-TDAPA add-on payment adjustment amounts from year-to-year, or from the proposed rule to the final rule, are driven by changes in utilization and price for the drug or biological product in question. We invite public comments on our proposed CY 2026 post-TDAPA add-on payment adjustment amounts.

b. Proposed Technical Correction to 42 CFR 413.234(g)(5)

We are proposing to modify the language at § 413.234(g)(5) to fix a typographical error in the spelling of the word “adjusted”. We welcome public comments on this proposed change or any other areas where the regulatory language should be corrected.

7. Proposed Changes to the TDAPA Eligibility Criteria

a. Background on the TDAPA

Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous (IV) products into the ESRD PPS bundled payment. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process that allowed us to recognize when an oral-only renal dialysis service drug or biological product is no longer oral-only, and a process to include new injectable and IV products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount.

The processes we finalized in the CY 2016 ESRD PPS final rule are based on whether a drug or biological product fits within one of eleven ESRD PPS functional categories. These ESRD PPS functional categories, which were first

established in the CY 2011 ESRD PPS final rule, represent all of the drugs and biological products included in the ESRD PPS bundled payment, as well as those receiving the transitional drug add-on payment adjustment (TDAPA) (80 FR 69013 through 69027). As we established in the CY 2011 ESRD PPS final rule, categorizing drugs and biological products on the basis of drug action allows us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047). We grouped the injectable and IV drugs and biological products into functional categories based on their action (80 FR 69014). This was done for the purpose of adding new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. We finalized the definition of an ESRD PPS functional category in our regulations at § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

In the CY 2016 ESRD PPS final rule, we established a requirement at § 413.234(b)(2) that, if a new injectable or IV product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product

is paid for using the transitional drug add-on payment adjustment (TDAPA) described in § 413.234(c). Then, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

We finalized in the CY 2016 ESRD PPS final rule that the TDAPA provides additional payment for certain new drugs and biological products. Under § 413.234(c), the TDAPA is based on pricing methodologies under section 1847A of the Act and is paid until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than two years. During the time a new injectable or IV product is eligible for the TDAPA, it is not eligible as an outlier service. Following payment of the TDAPA, the ESRD PPS base rate would be modified, if appropriate, to account for the new injectable or intravenous product in the ESRD PPS bundled payment.

In the CY 2019 ESRD PPS final rule (83 FR 56927 through 56949), CMS expanded the TDAPA to all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories. For new renal dialysis drugs or biological products that do not fall within an ESRD PPS functional category, we specified that the ESRD PPS base rate would not be modified after the two-year TDAPA period (83 FR 56943), but, as consistent with the existing outlier policy, the drug or biological product would be eligible for outlier payment unless it is a composite rate drug. In this rule, we modified the definition of “new renal dialysis drug or biological product” at 413.234(a) to specify that the drug or biological product must be approved by the FDA on or after January 1, 2020. We also changed the basis of payment for

the TDAPA from pricing methodologies under section 1847A of the Act (which includes 106 percent of ASP) to 100 percent of ASP and updated the definitions of “new renal dialysis drug or biological product” and “oral-only drugs” under § 413.234(a).

In the CY 2020 ESRD PPS final rule (84 FR 60653 through 60681), CMS finalized the exclusion of generic drugs and certain NDA types from TDAPA eligibility to distinguish innovative from non-innovative renal dialysis drugs and biological products. As codified at § 413.234(e)(1) through § 413.234(e)(7), NDA Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the “parent NDA” is a Type 3, 5, 7 or 8, are excluded from TDAPA eligibility. Additionally, we finalized a policy to use Wholesale Acquisition Cost (WAC) if ASP data is not available, and if WAC is not available, to then use invoice pricing. We also finalized a policy to no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the 3rd calendar quarter after we begin applying the TDAPA for that product or if CMS does not receive the latest full calendar quarter of ASP data for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

The CY 2020 ESRD PPS final rule also established the transitional payment for new and innovative equipment and supplies (TPNIES), a non-budget neutral add-on payment adjustment for certain new and innovative equipment and supplies (84 FR 60681 through 60699). TPNIES is codified at § 413.236. When the TPNIES was established, the eligibility criteria at § 413.236(b)(2) defined “new” as receiving FDA marketing authorization on or after January 1, 2020. In the CY 2021 ESRD PPS final rule we modified the TPNIES eligibility criteria to reflect the definition of “new” to mean within 3 years beginning on the date of FDA marketing authorization (85 FR 71410 through 71414). In the CY 2024 ESRD PPS final rule, we revised § 413.236(b)(2) to further clarify that an equipment or supply for which a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization would be considered new (88 FR 71414 through 76415).

In both the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56927 through 56949; 84 FR 60653 through

60681), CMS explained that the aim of the TDAPA is to help ESRD facilities incorporate into their business model new drugs and biological products that fall within existing ESRD PPS functional categories by providing additional payments. We further explained that the TDAPA aims to promote competition among the products within the ESRD PPS functional categories and focus Medicare resources on products that are innovative. For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, we clarified that the TDAPA could be a pathway toward a potential base rate modification, if appropriate.

b. Proposed Modification to the Eligibility Timeframe for the TDAPA

In the CY 2019 ESRD PPS final rule, we explained that the main goals of the TDAPA are to promote the incorporation of new renal dialysis service drugs and biological products into the ESRD PPS bundled payment and to focus Medicare resources on new and innovative products (84 FR 60653). Under the current regulations, any renal dialysis drug or biological product that receives FDA approval on or after January 1, 2020, would be considered “new” under § 413.234(a) and would be eligible for the TDAPA if it meets the other criteria and is not excluded from TDAPA payment under § 413.234(e). When we finalized § 413.234(a) in the CY 2019 ESRD PPS final rule (83 FR 56932), we stated that we believed it was appropriate at that time to consider renal dialysis drugs and biological products to be considered new if they were approved after January 1, 2020. However, because the regulatory definition for “new renal dialysis drug or biological product” includes a specific date on which a drug or biological product may start to be considered new but does not specify a date when it is no longer considered new, the current regulatory definition of a new renal dialysis drug or biological product could apply to drugs with FDA approval dates that are increasingly old. For example, for CY 2026 and future years, a renal dialysis drug or biological product approved by FDA in 2020 would be over 5 years old. As the TDAPA currently has no other time-dependent eligibility requirements, that would mean there is the potential for increasingly older drugs to be eligible for and receive the TDAPA. As discussed in the CY 2019 ESRD PPS final rule, CMS grouped drugs and biological products into functional categories based on their action for the purpose of adding new drugs or

biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them (83 FR 56928). When CMS finalized the expansion of the TDAPA to all new renal dialysis drugs and biological products later in that same rule, one of the main goals was improving beneficiary access to new and innovative products. At the time of the TDAPA expansion, the January 1, 2020, timeframe for the regulatory definition of “new renal dialysis drug or biological product” aligned with this goal of TDAPA. However, we do not believe the original intention of this requirement was to ensure that renal dialysis drugs and biological products approved on or after January 1, 2020, would continue to be eligible for the TDAPA in perpetuity after their FDA approval. As noted previously, for the TPNIES, § 413.236(b)(2) provides that an equipment or supply for which a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization is considered new. In the CY 2021 ESRD PPS final rule, when CMS changed the TPNIES eligibility criteria set forth at § 413.236(b)(2), we stated that we did not believe newness should be tied to the effective date of the TPNIES, and that a three-year eligibility window would be consistent with the timeframe for the new-technology add-on payment (NTAP) under the IPPS (85 FR 71411 through 71412). Regarding the NTAP, § 412.87(b)(2) notes that a medical service or technology may be considered new within two to three years after it is released onto the open market. Consistent with the views that CMS expressed regarding the TPNIES eligibility timeframe in the CY 2021 ESRD PPS final rule, we believe that the continued use of the January 1, 2020, date for the TDAPA would allow for some renal dialysis drugs and biological products to potentially qualify for the TDAPA well after they are already established, which would conflict with CMS’ original intention for the TDAPA: to provide additional support to ESRD facilities during the uptake period for innovative drugs and biological products and help incorporate them into their business model (84 FR 60663).

We are proposing to modify the language of § 413.234 to reflect that a TDAPA application must be submitted within 3 years of FDA approval for a new renal dialysis drug or biological product to be eligible for the TDAPA. We are also proposing to restructure the

section to consolidate the TDAPA eligibility requirements in a new paragraph (c)(5) in § 413.234, since currently some TDAPA eligibility requirements are included in the definition of “new renal dialysis drug or biological product” and the requirement to submit a TDAPA application is not explicitly stated in the regulations. We note that we use the definition of “new renal dialysis drug or biological product” for the general drug designation process at § 413.234(b), so we believe it would be more appropriate to move the specific TDAPA eligibility requirements to § 413.234(c). When considering a potential timeframe for TDAPA eligibility, we believe it is important to consider the time and expense it takes for a drug to come to market to ensure that drug manufacturers have enough time to establish infrastructure to adequately produce and distribute the drug. Giving manufacturers sufficient time to plan the rollout of a new renal dialysis drug or biological product would help ensure that it is made available to ESRD facilities, and therefore ESRD patients, during the TDAPA period. We are proposing a 3-year timeframe for TDAPA eligibility as we believe three years strikes a balance between allowing drug manufacturers flexibility in the timing of the rollout for their new renal dialysis drugs and biological products and ensuring the TDAPA is only available for drugs and biological products that are new to the renal dialysis market. We note that three years is generally consistent with how “new” is defined at § 412.87(b)(2) for the NTAP and at § 413.236(b)(2) for the TPNIES, as mentioned previously. Because three years is the timeframe we currently use for assessing whether renal dialysis equipment and supplies are “new” for purposes of the TPNIES; this proposed change would also standardize the eligibility timeframe across both the TDAPA and the TPNIES under the ESRD PPS. We believe this proposed change aligns with the TDAPA goals to support innovation by providing additional payment to help ESRD facilities make appropriate changes in their businesses to adopt new drugs and biological products, incorporate these new drugs and biological products into their beneficiaries’ care plans, potentially promote competition among drugs and biological products within the ESRD PPS functional categories, and focus Medicare resources on products that are innovative (83 FR 56935; 84 FR 60654 through 60665). To implement this change, we propose the following changes: (1) to add a new paragraph

§ 413.234(c)(5) which would include the eligibility requirements specific to TDAPA; (2) to revise the definition of “new renal dialysis drug or biological product” to remove the eligibility requirements for TDAPA related to having a HCPCS level II application; and (3) to revise the language at § 413.234(b)(1)(ii) and § 413.234(b)(2)(ii) to reference this new paragraph (c)(5). We are not proposing to remove the commercial eligibility requirement from the definition of “new renal dialysis drug or biological product” as that would have implications on the ESRD PPS drug designation process and the post-TDAPA add-on payment adjustment, which is not our intention. We note that a drug or biological product must meet the definition of “new renal dialysis drug or biological product” to be eligible for the TDAPA, and that the intention of proposing to move the eligibility requirements specific to TDAPA to the new paragraph is to make it clearer which requirements relate to the TDAPA, and which requirements relate to the definition of “new renal dialysis drug or biological product.”

We propose that this new paragraph, § 413.234(c)(5), would specify the current eligibility criteria and the proposed TDAPA eligibility timeframe for new renal dialysis drugs or biological products that have submitted TDAPA applications either within three years of FDA approval or prior to January 1, 2028. This paragraph would include the requirement that an application be submitted for the TDAPA, which reflects current policy but is not currently specified in the regulation.

We are proposing the 3-year timeframe for TDAPA eligibility would apply for renal dialysis drugs and biological products for which a TDAPA application is submitted on or after January 1, 2028. We are proposing this later implementation date as we recognize that there may be renal dialysis drugs or biological products which were approved by the FDA on or after January 1, 2020, and before January 1, 2023, but for which a TDAPA application has not yet been submitted due to the established eligibility criteria in § 413.234(a), although we note that we have not identified any such drugs or biological products. If we were to finalize this policy effective January 1, 2026, any such renal dialysis drugs and biological products would no longer be eligible for the TDAPA because they would no longer be within the three-year window of FDA approval. Our experience has been that manufacturers generally apply for the TDAPA within

the first few months after receiving FDA approval for their products; therefore, we believe that any renal dialysis drugs or biological products approved by the FDA between January 1, 2020, and January 1, 2023, for which a TDAPA application has not yet been submitted would be limited. However, it is not our intention with this proposed policy to prevent existing renal dialysis drugs or biological products which would be eligible for the TDAPA under the current eligibility requirements from receiving the TDAPA. Our proposed changes to § 413.234, specifically our proposed addition of § 413.234(c)(5)(ii), as discussed previously, provides that the three-year window would begin to apply for applications received on or after January 1, 2028. This would provide ample time for any manufacturer of a renal dialysis drug or biological product that received FDA approval between January 1, 2020, and January 1, 2025, to apply for the TDAPA. We note that any drug or biological product which was approved by the FDA more than three years prior to January 1, 2028, should submit their application for the TDAPA prior to January 1, 2028. If this condition and the other requirements are met, such drugs or biological products would still receive a full two-year TDAPA period as specified at § 413.234(c)(1) or a full period of at least two years as specified at § 413.234(c)(2). Renal dialysis drugs and biological products that CMS previously approved for the TDAPA and were paid for using the TDAPA period prior to January 1, 2028, would not be affected by this proposed change. We also note that our proposed change to the TDAPA eligibility timeframe would apply to all new renal dialysis drugs and biological products that are potentially eligible for the TDAPA in the future, including those that fall into existing ESRD PPS functional categories, and those that would fall into new functional categories.

Table 5 presents hypothetical situations in which renal dialysis drugs and biological products that received FDA approval before and after January 1, 2025, would or would not be eligible for the TDAPA under the proposed changes to the TDAPA eligibility criteria. CMS reiterates that renal dialysis drugs and biological products that CMS previously approved for the TDAPA and that were paid for using the TDAPA period prior to January 1, 2028, would not be affected by this proposed change. As noted previously, if a renal dialysis drug or biological product that received FDA approval more than three years prior to January 1, 2028, submits

a TDAPA application prior to January 1, 2028, the TDAPA would still be paid for a full two-year period as specified at § 413.234(c)(1) or a full period of at least two years as specified at § 413.234(c)(2), provided all other applicable requirements in § 413.234 are met.

TABLE 5—HYPOTHETICAL TDAPA-ELIGIBILITY SCENARIOS UNDER THE PROPOSED CHANGES TO THE TDAPA ELIGIBILITY CRITERIA

Hypothetical new renal dialysis drug or biological product FDA approval date	Hypothetical TDAPA application submission date	TDAPA eligibility under the proposed changes
January 10, 2020	December 10, 2027	Eligible.
January 10, 2020	January 2, 2028	Not Eligible.
January 20, 2025	January 19, 2028	Eligible.
January 20, 2025	January 21, 2028	Not Eligible.

We are soliciting comments on all aspects of this proposal, including the proposed 3-year eligibility window, our proposal to apply this change to new renal dialysis drugs and biological products in both existing and new ESRD PPS functional categories, and the proposed CY 2028 implementation date of the policy. Additionally, we are soliciting comments on the TDAPA eligibility requirements more broadly and welcome any suggestions on how our TDAPA policies could be improved in future rulemaking.

8. Proposed Payment Adjustment for ESRD Facilities in Certain Non-Contiguous States and Territories

a. Background

As set forth in § 413.230, the ESRD PPS per treatment payment amount is calculated as the sum of the ESRD PPS base rate, the wage index for the ESRD facility and various patient-level and facility-level payment adjustments, and any applicable outlier payments and add-on payment adjustments which are described previously in this proposed rule. The ESRD PPS wage index is intended to reflect the relative cost of the labor utilized for renal dialysis services in the geographic area in which an ESRD facility is located and is applied to the labor-related share of the ESRD PPS base rate, as defined at § 413.231. In the CY 2025 ESRD PPS final rule, we finalized a new methodology for determining the wage index value for an ESRD facility (89 FR 89116). This methodology uses data from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS), weighted according to an occupational mix derived from freestanding ESRD facility cost reports, to better estimate the actual labor costs ESRD facilities incur when furnishing renal dialysis services. A summary of this methodology is available in section II.B.2. of this proposed rule. The ESRD PPS wage index and the other payment adjustments, which include case-mix

adjusters, facility level adjustments and add-on payment adjustments, serve to better align relative ESRD PPS payments with relative resource use. These payment adjustments are generally established under section 1881(b)(14)(D) of the Act, which lists several payment adjustments that the Secretary is required or authorized to include in the ESRD PPS.

In the CY 2025 ESRD PPS proposed rule, we discussed the impacts of the proposed new ESRD PPS wage index methodology in more detail (89 FR 55778 through 55780). Specifically, we discussed the regional impact of the then-proposed methodology. We stated that as this methodology better estimates the wage costs for ESRD facilities, and we believed the regional impacts of the new methodology are generally appropriate as they align wage-adjusted payments with relative labor costs. We requested public comment on the regional implications of the proposed policy. As a part of this request for public comment, we highlighted the potential impacts for the U.S. Pacific Territories, which were larger in magnitude compared to most other regions. In response, we received two comments that expressed concerns specifically with the impact of the wage index proposal on the U.S. Pacific Territories, one of which was a letter from interested parties representing Guam, American Samoa, and the Northern Mariana Islands (89 FR 89114). These comments expressed specific concern with the projected payment decrease for these territories associated with the proposed policy and noted that these isolated island territories had higher costs than other regions for certain goods and services.

The letter from the interested parties representing Guam, American Samoa, and the Northern Mariana Islands also built upon concerns raised by multiple commenters, including MedPAC in its

June 2020 Report to Congress,⁹ reiterating that the current ESRD PPS payment adjustments, including the LVPA, do not accurately target remote or isolated facilities. We note that past commenters have used differing definitions of these terms. The interested parties requested CMS to consider factors that are unique to small island economies such as air freight shipping, greater utility costs, difficulty recruiting and retaining qualified healthcare professionals, and lack of economies of scale when compared to larger ESRD facilities located in the contiguous U.S. Those parties requested that the Secretary establish a new payment adjustment for the U.S. Pacific Territories, outside of the LVPA, to account for the higher cost of providing renal dialysis services in some of the most remote areas of our country. In the CY 2025 ESRD PPS final rule, we responded to these comments by acknowledging that these remote territories may have some higher costs, but noted that most of the goods and services these comments cited were generally not labor-related and therefore, it would be inappropriate to consider them in constructing a wage index value for the region (89 FR 89114 through 89115). While we did make changes to the LVPA in the CY 2025 ESRD PPS final rule, we did not discuss or finalize any change which would address higher costs in remote areas during the CY 2025 rulemaking cycle. As we explained in the CY 2024 ESRD PPS proposed rule (88 FR 42441), our analysis has not found higher costs associated with low-volume facilities in remote areas (including areas in the contiguous U.S.), although we note that the analysis referenced in that rule used a metric for isolation based on distance to the nearest ESRD facility and did not consider remote states or territories separately.

⁹ https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_reporttocongress_sec.pdf.

b. Estimating the Extent to Which ESRD Facilities in Non-Contiguous Areas Face Higher Non-Labor Costs Than ESRD Facilities Located in the Contiguous U.S.

As noted in the CY 2025 ESRD PPS final rule, we believe that the new ESRD PPS wage index methodology better estimates the relative labor costs faced by ESRD facilities, and any changes in payment associated with the new wage index methodology were generally appropriate (89 FR 89108 through 89117). However, we recognize the possibility that an ESRD facility could have certain unrecognized costs which are not accounted for by any of the existing payment adjustments under the ESRD PPS. As a result of the comments on the CY 2025 ESRD PPS proposed rule, we have conducted an analysis of non-labor costs in certain remote areas of the United States. We included Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands in this analysis in addition to Guam, American Samoa, and the Northern Mariana Islands so that we could evaluate any potential higher non-labor costs in other non-contiguous areas relative to the contiguous U.S. We evaluated all of the non-contiguous areas as the higher non-labor costs mentioned by commenters could have been experienced in other non-contiguous areas outside of just the U.S. Pacific Territories. We note that when we refer to “U.S. Pacific Territories” in the context of this proposed rule, we are specifically discussing the three permanently inhabited U.S. Territories in the Pacific region surveyed by the Census Bureau’s Island Areas Census ¹⁰ and served by the Office of the Insular Affairs,¹¹ which are Guam, American Samoa and the

Northern Mariana Islands. None of the other U.S. Territories located in the Pacific region have Medicare-certified ESRD facilities and, as such, were not considered for the purposes of this analysis. Should an ESRD facility open in another U.S. Pacific Territory we would consider whether it would be appropriate to extend any existing geographic payment adjustments that apply to other U.S. Pacific Territories, such as the payment adjustment proposed in section II.B.7.c of this proposed rule (should that payment adjustment be finalized), to such territory in future rulemaking.

To estimate the extent to which ESRD facilities in certain remote areas face higher costs after accounting for the ESRD PPS wage index, we focused the analysis on the &portion of the costs faced by ESRD facilities that are non-labor related. This analysis used data from freestanding and hospital-based ESRD facility cost reports from cost reporting years beginning between January 1, 2020, and December 31, 2022. For the purpose of this analysis, the non-labor costs associated with furnishing renal dialysis services include the non-salary costs associated with capital, administration, drugs, supplies and laboratory tests from Medicare cost reports.¹² We recognize that some parts of these cost categories could overlap with cost categories included in the labor-related share; for example, capital costs include both the materials and labor involved in constructing buildings. However, given the limitation of cost report data available for this analysis, we believe including these non-direct labor costs provided a more accurate result.

The analysis conducted was a logarithmic regression which used

facility-level average non-labor cost per treatment as the dependent variable. As cost report data includes both Medicare and non-Medicare dialysis treatments and costs, this analysis also encompasses all treatments furnished by ESRD facilities. We controlled for various facility-level characteristics including log quadratic facility treatment volume, rurality, wage index value, ownership-type, percent of treatments which are Medicare treatments, percent of treatments which are home dialysis treatments, average case-mix adjustment multiplier for Medicare treatments, an indicator for whether the facility furnished more than 20 percent of its treatments to pediatric patients, and indicators for cost report year. The treatment variables were a variety of indicators for non-contiguous geographic areas including Alaska, Hawaii, Guam, American Samoa, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands. To avoid issues with small sample size, we combined the U.S. Pacific Territories of Guam, American Samoa, and the Northern Mariana Islands in one group and the U.S. Caribbean Territories of Puerto Rico and the U.S. Virgin Islands into another group. We believe that these groupings are reasonable due to the similar nature of the territories within each group in terms of their geographic isolation. To avoid undue influence of very large and small ESRD facilities, we removed data from ESRD facilities in the top and bottom 2.5 percent of cost per treatment and facility size. The regression yielded the relative cost for each state or group of territories when compared to the contiguous United States. The results of the regression are presented in Table 6.

TABLE 6—NON-LABOR COSTS FOR CERTAIN NON-CONTIGUOUS AREAS RELATIVE TO THE CONTIGUOUS U.S.

State or group of territories	Number of ESRD facilities	Regression result	Standard deviation	Relative non-labor cost to contiguous US (%)
Alaska	9	0.490	0.071	56
Hawaii	41	0.205	0.032	21
Guam, Northern Mariana Islands, American Samoa	11	0.294	0.054	31
Puerto Rico, U.S. Virgin Islands	54	* –0.052	0.035	–5

* **Note:** this relative cost factor was found to be statistically non-significant for this group.

The first column in Table 6 lists the states or groups of territories which we analyzed in reference to the contiguous

U.S. The second column lists the number of freestanding and hospital-based ESRD facilities in each of those

non-contiguous areas. The third and fourth columns show the coefficients of the logarithmic regression and the

¹⁰ <https://www.census.gov/programs-surveys/decennial-census/decade/2020/planning-management/release/2020-island-areas-data-products.html>.

¹¹ <https://www.doi.gov/oia/islands>.

¹² Cost data from freestanding ESRD facility cost reports (form CMS 265–11) are from Worksheet B, lines 8 through 17.02, columns 3, 4, 7, 8, 9, 11, 12, 13. Cost data from hospital-based ESRD facility cost reports (form CMS 2552–10) are from Worksheet I–2, lines 2 through 11.01, columns 1, 2, 6, 7, 8, & 10, and lines 14 through 16, column 6.

standard deviations of the coefficients, respectively. The final column shows the relative non-labor costs for each non-contiguous area derived from this regression. As this was a logarithmic regression, the natural logarithm used in the regression model is a tool to make the data more amenable to linear analysis. After obtaining the regression coefficients, the exponential function with base e (mathematical constant) is used to interpret and predict values on the original scale. This analysis shows that ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories each have higher non-labor costs than ESRD facilities in the contiguous U.S. after controlling for the ESRD facility characteristics described previously. ESRD facilities in Puerto Rico and the U.S. Virgin Islands did not demonstrate higher non-labor costs compared to ESRD facilities in the contiguous U.S. Alaska had the highest non-labor costs at 56 percent higher relative to the contiguous U.S., followed by the U.S. Pacific Territories at 31 percent higher, and Hawaii at 21 percent higher. This logarithmic regression analysis had an adjusted R-squared value of 0.473, which indicates that the analyzed variables (including the constants) account for 47.3 percent of the variation in the mean non-labor costs per treatment. The p-values for the regression result for Alaska, Hawaii and the U.S. Pacific Territories were each significant at the one percent level, which means there is a less than one percent chance that the results of the regression were due to random variation. Based on these results, we believe there is reasonable evidence that ESRD facilities in these non-contiguous areas face higher non-labor costs compared to ESRD facilities in the contiguous U.S. after controlling for the ESRD facility characteristics described previously. As noted in the footnote on Table 6, the regression result for the U.S. Caribbean Territories of Puerto Rico and the U.S. Virgin Islands is relatively close to zero and was not significant; so, although it is negative (indicating lower non-labor costs compared to ESRD facilities in the contiguous U.S. after controlling for the ESRD facility characteristics described previously) we cannot be confident that these ESRD facilities have lower average non-labor costs based on this analysis alone.

c. Proposal for a Non-Contiguous Area Payment Adjustment (NAPA)

As discussed previously, we have found that ESRD facilities in certain remote non-contiguous geographic areas have some higher non-labor costs when

compared to the contiguous United States. Currently, these higher non-labor costs are generally not accounted for by the ESRD PPS, with some exceptions. The LVPA likely covers some of the non-labor costs associated with being in a non-contiguous area, as some of the additional costs in these areas are likely due to higher costs for certain goods, which, as defined in section 1881(b)(14)(D)(iii) of the Act, the LVPA is intended to help mitigate through additional payment. However, our review has not found substantial overlap between non-contiguous areas and low-volume facilities as defined at § 413.232(b). Additionally, the rural facility adjustment likely accounts for some of the higher costs for these remote areas, although the magnitude of the rural facility adjustment is much smaller than the LVPA, so it cannot account for all of the aforementioned higher non-labor costs.

Under the authority of section 1881(b)(14)(D)(iv) of the Act, we are proposing a new facility-level payment adjustment for ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories, which, as described previously, were found to have higher non-labor costs when compared to ESRD facilities in the contiguous U.S. We refer to this proposed payment adjustment as the non-contiguous areas payment adjustment (NAPA) in this CY 2026 ESRD PPS proposed rule. The NAPA would apply only to the non-labor portion of the ESRD PPS base rate, which is 44.8 percent. As proposed, the magnitude of this proposed NAPA would be dependent on which of the non-contiguous remote areas a given ESRD facility is located in. We are also proposing for the NAPA to be applied budget-neutrally, consistent with the longstanding framework within the ESRD PPS to apply any payment adjustment that accounts for costs which were originally included in the analysis used for the CY 2011 ESRD PPS final rule in a budget-neutral manner (88 FR 42451). We are proposing that the NAPA would apply to all ESRD PPS claims for renal dialysis services furnished by ESRD facilities in these non-contiguous areas, including treatments furnished at home and to pediatric ESRD beneficiaries, as we have no evidence to indicate these higher non-labor costs would be unique to adult or in-center ESRD treatments.

When developing the methodology for calculating the proposed NAPA, we considered the results of our analysis as outlined in Table 6. We also considered the potential impact to the proposed ESRD PPS base rate, since we are proposing for this proposed payment

adjustment to be applied budget-neutrally, as noted in the prior paragraph. We considered applying the adjustment factors (calculated as 1 + percentages in Table 6) to the non-labor-related portion of the base rate for treatments provided in Alaska, Hawaii, and the U.S. Pacific Territories, which we estimate would require a reduction to the ESRD PPS base rate of approximately 0.2 percent, or \$0.47. Given the potential impact to ESRD facilities across the country, we believe it would be appropriate to consider policies that would lessen the potential base rate reduction associated with the proposed NAPA.

We considered policies that have historically been applied in other Medicare payment systems which apply a geographical adjustment for non-labor costs. The IPPS has a Cost-of-Living Adjustment (COLA) for Alaska and Hawaii which is an upwards adjustment factor that applies to the non-labor-related portion of the standardized amount for hospitals and is capped at 25 percent (89 FR 69964, 77 FR 53700 through 53701). We believe that a functionally similar cap would be appropriate for the proposed NAPA for several reasons. First, given the small number of ESRD facilities included in this regression analysis, there is inherent uncertainty in the result of the regression analysis. Additionally, applying a cap to the proposed NAPA would minimize the financial impact to ESRD facilities located in the contiguous U.S. while providing a substantial upward adjustment for ESRD facilities located in Alaska, Hawaii, and the U.S. Pacific Territories, which our analysis demonstrates have significantly higher non-labor costs compared to the contiguous U.S. We examined multiple different data points when determining what level of cap would be the most appropriate for the proposed NAPA, and while there is no one superior methodology from which to derive a cap for the proposed NAPA, as it is intended to account for non-labor costs, we believe it would be appropriate to consider such a payment adjustment in reference to the impact of the ESRD PPS wage index. Specifically, we believe that the impact of the NAPA on non-labor costs should not exceed the impact of the wage index on labor-related costs. Although the wage index and the NAPA account for different types of costs, they both intend to account for the variation in costs based on geographic factors. Additionally, interested parties' concerns about the finalized wage index changes in the CY 2025 ESRD PPS final rule prompted our

analysis of non-labor costs in non-contiguous areas. We believe the former ESRD PPS wage index methodology for the U.S. Pacific Territories was providing additional payment for ESRD facilities in these areas above the amount that is attributable to labor costs in these areas, while the ESRD PPS in general did not account for those areas' relatively higher non-labor costs. Therefore, this higher labor-related payment was potentially compensating for the higher non-labor costs that ESRD facilities in these areas faced. A reasonable upward bound for NAPA would be to align the maximum payment increase under NAPA to be approximately equal to that of the higher wage index values. To avoid undue influence of outliers, we considered a potential NAPA cap based on the 95th percentile of wage index values, which is based on the CY 2026 proposed ESRD PPS wage index is 1.209945. Because the non-labor-related share is slightly smaller than the labor-related share to which the wage index applies, a NAPA value that equals the payment impact of this wage index value is 1.258682.¹³ For simplicity, we are rounding this value to 25 percent which is also consistent with the IPPS COLA cap previously discussed.

In comparison to the uncapped NAPA, if we were to apply a 25 percent cap to the NAPA, we estimate the required reduction to the base rate would be notably less at approximately 0.1 percent, or \$0.35. We believe this more moderate reduction to the ESRD PPS base rate would better allow ESRD facilities in contiguous areas to continue to provide high-quality care while better aligning payments to ESRD facilities in non-contiguous areas with their relatively higher non-labor costs.

Therefore, under the proposed NAPA, ESRD facilities in these selected geographies would receive up to a 25 percent increase to the non-labor portion of the ESRD PPS bundled payment as determined by the latest available analysis. We believe implementing such a payment adjustment with a 25 percent cap would strike an appropriate balance between increasing payments to areas for which we have evidence of relatively higher non-labor costs and mitigating the impact of this payment adjustment on

ESRD facilities located in the contiguous U.S. and the Caribbean territories of Puerto Rico and the U.S. Virgin Islands. In addition, we believe the proposed capped NAPA is appropriate due to the potential for overlap with the other payment adjustments, such as the LVPA, that could account for other costs faced by ESRD facilities in high-cost non-contiguous states and territories. Table 7 summarizes the proposed NAPA factors effective for CY 2026. The budget neutrality factor for this proposed NAPA is 0.99859. We intend to review these adjustment factors and consider whether the proposed NAPA (if finalized) remains appropriate when we propose to update the labor-related share of the ESRDB market basket. If applicable, CMS would propose any changes to the NAPA methodology or adjustment factors in future notice-and-comment rulemaking.

TABLE 7—PROPOSED NAPA FACTORS FOR CY 2026

State or group of territories	Proposed NAPA factor
Alaska	1.25
Hawaii	1.21
Guam, Northern Mariana Islands, American Samoa	1.25

To implement this proposed new payment adjustment, we are proposing to rename 42 CFR 413.233 from "Rural facility adjustment" to "Additional facility-level adjustments." We are also proposing to designate a new paragraph (a) to include the current language of § 413.233. We are further proposing to add paragraph (b) to read "CMS adjusts the non-labor-related portion of the base rate for facilities in Alaska, Hawaii, Guam, American Samoa, and the Northern Mariana Islands". Lastly, we are proposing to modify § 413.230(a) to include § 413.233 in the list of facility-level adjustments.

We believe that this proposed new payment adjustment would better align payment with resource use in these non-contiguous remote geographic areas. We are requesting comment on this proposal, including the magnitude of the proposed adjustment, implementing the proposed NAPA with a 25 percent cap on the adjustment factors, the budget neutrality of the proposal, the proposed application of NAPA to payments for Pediatric ESRD Patients as defined in § 413.171, the proposed application of NAPA to payment for home dialysis treatments, and the proposed changes to §§ 413.230(a) and 413.233.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, to support ESRD facility use and beneficiary access to these new items.

We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES. Under current § 413.236(b), CMS provides for a TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a complete HCPCS Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for non-drug and non-biological items, supplies, and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular CY; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1); and (6) is not a capital-related asset, except for capital-related assets that are home dialysis machines. For additional background on the TPNIES, we refer readers to the CY 2024 ESRD PPS final rule (88 FR 76410 through 76412).

As indicated in § 413.236(c) CMS includes the summary of each TPNIES application and our analysis of the eligibility criteria for each application in the annual ESRD PPS proposed rule and announces the results in the annual ESRD PPS final rule. Because we did not receive any applications for the TPNIES for CY 2026, we have not included any TPNIES application summaries, CMS analyses, or results in this proposed rule.

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2026

In this section of the proposed rule, we identify any items previously approved for the TPNIES and for which

¹³ This is calculated by comparing payment using a wage index value of 1.209945 and a NAPA factor of 1 to payments using a wage index value of 1 and a NAPA factor of x: Base rate*0.552*1.209945 + Base rate*0.448*1 = Base rate*0.552*1 + Base rate*0.448*x. We note that in this formula the base rate is equally applied to every term and cancels out, so the derived x=1.258682 is not dependent on the ESRD PPS base rate value.

payment is continuing for CY 2026. As described in the CY 2025 ESRD PPS final rule, no new items were approved for the TPNIES for CY 2025 (89 FR 89162 through 89163). As such there are no items previously approved for the TPNIES for which payment is continuing in CY 2026.

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2026

Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. In April 2024, CMS approved DefenCath® (taurolidine and heparin sodium) for the TDAPA under the ESRD PPS, effective July 1, 2024. Implementation instructions are specified in CMS Transmittal 12628, dated May 9, 2024, and available at <https://www.cms.gov/files/document/r12628CP.pdf>.

In October 2024, CMS approved Vafseo® (vadadustat) for the TDAPA under the ESRD PPS, effective January

1, 2025. In addition, the following oral-only phosphate binders were also approved for the TDAPA under the ESRD PPS effective January 1, 2025: sevelamer carbonate, sevelamer hydrochloride, sucroferic oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate. These drugs were not considered included in the ESRD PPS bundled payment and were paid separately beginning in CY 2011 (75 FR 49037 through 49053). In the CY 2023 ESRD PPS final rule, we stated that if no other injectable equivalent (or other form of administration) of phosphate binders is approved by the FDA prior to January 1, 2025, we would pay for these drugs using the TDAPA under the ESRD PPS for at least 2 years beginning January 1, 2025 (87 FR 67180).

The implementation instructions for drugs with a TDAPA effective date of January 1, 2025, were specified in CMS Transmittal 12962 dated November 14, 2024, and available at <https://www.cms.gov/files/document/r12962bp.pdf>. This Change Request was

subsequently rescinded and replaced by Transmittal 12999, dated December 12, 2024, and available at <https://www.cms.gov/files/document/r12999bp.pdf>.

Table 8 identifies the two new renal dialysis drugs for which the TDAPA payment period as specified in § 413.234(c)(1) would continue in CY 2026: DefenCath® (taurolidine and heparin sodium) and Vafseo® (vadadustat). In addition, while the phosphate binders are not new renal dialysis drugs or biological products as specified in § 413.234(c)(1), the TDAPA payment period for sevelamer carbonate, sevelamer hydrochloride, sucroferic oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate would also continue in CY 2026. As noted previously, we would pay for the oral only phosphate binders using the TDAPA under the ESRD PPS for at least 2 years. Table 8 also identifies the products' HCPCS coding information as well as the payment adjustment effective dates and available end dates.

TABLE 8—CONTINUATION OF APPROVED TRANSITIONAL DRUG ADD-ON PAYMENT ADJUSTMENTS

HCPCS code	Long descriptor	Payment adjustment effective date	Payment adjustment end date
J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis).	7/1/2024	6/30/2026.
J0901	Vadadustat, oral, 1 mg (for ESRD on dialysis)	1/1/2025	12/31/2026.
J0601	Sevelamer carbonate (Renvela or therapeutically equivalent), oral, 20 mg (for ESRD on dialysis).	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0602	Sevelamer carbonate (Renvela or therapeutically equivalent), oral, powder, 20 mg (for ESRD on dialysis).	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0603	Sevelamer hydrochloride (Renagel or therapeutically equivalent), oral, 20 mg (for ESRD on dialysis).	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0605	Sucroferic oxyhydroxide, oral, 5 mg (for ESRD on dialysis)	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0607	Lanthanum carbonate, oral, 5 mg (for ESRD on dialysis)	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0608	Lanthanum carbonate, oral, powder, 5 mg, not therapeutically equivalent to J0607 (for ESRD on dialysis).	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0609	Ferric citrate, oral, 3 mg ferric iron, (for ESRD on dialysis)	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0615	Calcium acetate, oral, 23 mg (for ESRD on dialysis)	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.

III. CY 2026 Payment for Renal Dialysis Services Furnished to Individuals With AKI

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section

1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor

under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1861(s)(2)(F) of the Act, including the payment rate for AKI dialysis furnished by ESRD facilities (81 FR 77866 through 77872 and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the

ESRDB market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965). In the CY 2025 ESRD PPS final rule we finalized a policy to allow for payment for home dialysis for beneficiaries with AKI. Additionally, we extended the payment adjustment for home and self-dialysis training to AKI dialysis payments in a budget neutral manner and calculated a reduction to the AKI dialysis payment rate which rounded to \$0.00 (89 FR 89170).

B. Proposed Update of AKI Dialysis Payment

1. Proposed CY 2026 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual market basket update, geographic wage adjustments, and any other amounts deemed appropriate by the Secretary, for such year. We note that ESRD facilities could bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis. As discussed in section II.B.4. of this proposed rule, the proposed ESRD PPS base rate is \$281.06, which reflects the application of the proposed CY 2026 wage index budget neutrality adjustment factor of 1.00872, the application of the proposed budget neutrality factor for the proposed non-contiguous areas payment adjustment (NAPA) of 0.99859 discussed in section II.B.8. of this proposed rule, and the proposed CY 2026 ESRDB market basket percentage increase of 2.7 percent reduced by the proposed productivity adjustment of 0.8 percentage point, that is, 1.9 percent. Accordingly, we are proposing a CY 2026 per treatment payment rate of \$281.06 $((\$273.82 \times 1.00872 \times 0.99859) \times 1.019 = \$281.06)$ for renal dialysis services furnished by ESRD facilities to individuals with AKI. As discussed in section II.B.1. of this proposed rule, we are proposing that if more recent data become available after the publishing of this proposed rule and before the publishing of the final rule, we would use such data, if appropriate, to determine the CY 2026 ESRDB market basket percentage increase and productivity adjustment in the final rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRDB market basket percentage increase and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS. As discussed in section II.B.2.a. of this proposed rule, the ESRD PPS wage index is based on mean hourly wage data from the BLS OEWS weighted by FTE data from freestanding ESRD facility cost reports. We finalized the new methodology for determining the wage index value for an ESRD facility in the CY 2025 ESRD PPS final rule, (89 FR 89116). Accordingly, we applied the same wage index under § 413.231 that is used under the ESRD PPS to the AKI dialysis payment (89 FR 89167). We propose to continue using this same methodology when adjusting AKI dialysis payments to ESRD facilities, consistent with our historical practice of using the ESRD PPS wage index for AKI dialysis payments. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that ESRD facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. We also apply the wage index policies regarding the 0.600 wage index floor (87 FR 67161 through 67166) and the 5 percent cap on wage index decreases (87 FR 67159 through 67161) to AKI dialysis payments to ESRD facilities. ESRD facilities would utilize the same staff to provide renal dialysis services to and educate beneficiaries with AKI as those beneficiaries with ESRD. Therefore, utilizing the same wage index methodology would be appropriate in accordance with § 413.372, which addresses the payment rate for AKI dialysis and refers to § 413.231 for the wage adjustment. As stated previously, we are proposing a CY 2026 AKI dialysis payment rate of \$281.06, adjusted by the ESRD facility's wage index. As discussed in section II.B.2.c. of this proposed rule, we are proposing that if more recent data become available after the publishing of this proposed rule and before the

publishing of the final rule, we would use such data, if appropriate, to determine the CY 2026 update the ESRD PPS wage index.

3. Other Adjustments to the AKI Dialysis Payment Rate

Section 1834(r)(1) of the Act also provides that the payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act. As discussed in the CY 2025 ESRD PPS final rule, we have extended the home and self-dialysis training add-on payment adjustment under the ESRD PPS to AKI beneficiaries in a budget neutral way (89 FR 89170). We continue to collect data on the uptake of home dialysis treatments for beneficiaries with AKI. We are not proposing to reevaluate the budget neutrality factor for CY 2026.

We considered implementing the proposed new ESRD PPS facility-level payment adjustment for ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories, which we refer to in this proposed rule as the non-contiguous areas payment adjustment (NAPA), for beneficiaries with AKI. However, section 1834(r)(1) of the Act indicates that adjustments to AKI dialysis payments, other than the ESRD PPS wage index, must be made budget neutrally across AKI dialysis payments. We made a budget neutral adjustment to the AKI dialysis payment rate to account for the home and self-dialysis training payment adjustment in the CY 2025 ESRD PPS final rule (89 FR 89170). We are in the process of evaluating the effect of training adjustment on AKI dialysis payments. We do not believe it would be appropriate to propose any additional updates to the AKI dialysis payment rate at this time. However, we welcome comments from interested parties on the potential for other geographic payment adjustments to the AKI dialysis payment rate.

IV. Proposed Updates to the End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the citations provided at IV.A. of the CY 2024 ESRD PPS final rule (88 FR 76433). We have also codified many of our policies for

the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Proposed Updates to Requirements Beginning With the PY 2027 ESRD QIP

1. Proposed Removal of the Facility Commitment to Health Equity Reporting Measure Beginning With the PY 2027 ESRD QIP

We refer readers to the CY 2024 ESRD PPS final rule where we adopted the Facility Commitment to Health Equity reporting measure into the ESRD QIP (88 FR 76437 through 76446). We propose to remove the Facility Commitment to Health Equity measure beginning with the PY 2027 ESRD QIP. The perceived costs associated with achieving a high score on the measure outweigh the benefit of its continued use in the program. When adopted, we intended the collection of data described in the five domains of this measure to provide individual dialysis facility leadership with meaningful and actionable health data to drive quality improvements to eliminate health disparities. Based on feedback received from dialysis facilities as well as a continued focus on clinical outcome measures, the burden of collecting data for this measure may outweigh the benefits.

One of the goals of the ESRD QIP is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. Removing this measure from the ESRD QIP is one way to accomplish this goal. Our priority is a continued focus on measurable clinical outcomes as well as identifying quality measures on the topics of prevention, nutrition, and well-being. As such, we refer readers to our request for comment on “Request for Information on Measure Concepts under Consideration for Future Years” in section IV.D.2. of this proposed rule. With the entire set of measures, the ESRD QIP continues to incentivize the improvement of dialysis care quality and health outcomes for all patients through measurement and transparency. It may be costly for dialysis facilities to continue reporting on the Facility Commitment to Health Equity reporting measure and achieve high performance scores, and removal of this measure would make room both in the program’s measure set to enhance the program’s focus on other clinical outcomes and for dialysis facility leadership to focus on other priority quality and safety areas. Facilities that have already invested resources to meet

this measure’s requirements will still find value in this proposal through the reduction in reporting obligations if the measure is eliminated. Facilities would continue to benefit from this reduced administrative burden each year beginning with PY 2027, and the cumulative effect of this benefit over time is likely to outweigh resources expended in response to this measure.

We note that, since facilities have already submitted Facility Commitment to Health Equity reporting measure data for PY 2026, such measure data and scoring information will be available on the CMS Provider Data Catalog (PDC) and will be used for PY 2026 payment determinations. However, any Facility Commitment to Health Equity reporting measure data received by CMS for PY 2027 would not be used for public reporting or payment purposes. If finalized, facilities that do not report to CMS their PY 2027 reporting period data for the Facility Commitment to Health Equity reporting measure would not be penalized for PY 2027 scoring or payment purposes due to this measure.

We invite public comment on our proposal to remove the Facility Commitment to Health Equity reporting measure from the ESRD QIP beginning with the PY 2027 ESRD QIP.

2. Proposed Removal of the Two Social Drivers of Health Reporting Measures Beginning With the PY 2027 ESRD QIP

We propose to remove the two social drivers of health reporting measures from the ESRD QIP beginning with the PY 2027 ESRD QIP: Screening for Social Drivers of Health reporting measure (adopted at 88 FR 76466 through 76476); and Screen Positive Rate for Social Drivers of Health reporting measure (adopted at 88 FR 76476 through 76480). For further discussion of our previously established policies regarding measure adoption, retention, and removal, we refer readers to the CY 2024 ESRD PPS final rule (88 FR 76434).

We propose to remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with the PY 2027 ESRD QIP, under § 413.178(c)(5)(i)(H), Measure Removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. Although understanding the needs of patients receiving dialysis therapy is important, we have heard from some facilities concerned with the resources associated with screening patients via manual processes, manually storing such data, training facility staff, and altering workflows. Further, we note that these measures document an

administrative process and report aggregate level results, and do not shed light on the extent to which providers are ultimately connecting patients with resources or services and whether patients are benefiting from these screenings. We have concluded that the costs of the continued use of these measures in the ESRD QIP may outweigh the benefits to providers and patients. Removal of these measures would alleviate the burden on dialysis facilities to manually screen each patient and submit data each reporting cycle, allowing dialysis facilities to focus resources on other clinical outcomes. This will also remove the patient burden associated with repeated Social Drivers of Health screenings across multiple healthcare facilities. We refer readers to our request for comment, “Request for Information on Measure Concepts under Consideration for Future Years” in section IV.D.2. of this proposed rule for more information regarding our areas of focus for new measures. Facilities that have already invested resources to meet these measures’ requirements will still find value in this proposal through the reduction in reporting obligations if the measures are eliminated. Facilities would continue to benefit from this reduced administrative burden each year beginning with PY 2027, and the cumulative effect of this benefit over time is likely to outweigh resources expended in response to this measure. With the entire set of measures, the ESRD QIP continues to incentivize the improvement of dialysis care quality and health outcomes for all patients through measurement and transparency.

If finalized, facilities that do not report their PY 2027 measure data for the Screening for Social Drivers of Health reporting measure or the Screen Positive Rate for Social Drivers of Health reporting measure would not be penalized for PY 2027 scoring or payment purposes. In addition, any measure data received by CMS would not be used for public reporting or payment purposes.

We invite public comment on our proposal to remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure from the ESRD QIP beginning with the PY 2027 ESRD QIP.

C. Proposed Updates to Requirements Beginning With the PY 2028 ESRD QIP

1. PY 2028 ESRD QIP Measure Set

In this proposed rule, we are proposing to update the ICH CAHPS clinical measure beginning with the PY

2028 measure set. Table 9 summarizes the previously finalized and proposed updated measures that we would include in the PY 2028 ESRD QIP

measure set. The technical specifications for current measures that would remain in the measure set for PY 2028 can be found in the CMS ESRD

Measures Manual for the 2025 Performance Period.¹⁴

TABLE 9—PREVIOUSLY FINALIZED AND PROPOSED UPDATED MEASURES FOR THE PY 2028 ESRD QIP MEASURE SET

Consensus-based entity ¹⁵ (CBE) #	Measure title and description
0258 *	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure. Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple survey questions.
2496	Standardized Readmission Ratio (SRR), a clinical measure. Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on CBE #2979	Standardized Transfusion Ratio (STrR), a clinical measure. Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
Based on CBE #0323, # 0321, 2706, and #1423.	(Kt/V) Dialysis Adequacy Measure Topic, a clinical measure topic. Four measures of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. The individual Kt/V measures would be adult hemodialysis (HD) Kt/V, adult peritoneal dialysis (PD) Kt/V, pediatric HD Kt/V, and pediatric PD Kt/V.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure. Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a reporting measure. Percentage of patient-months with total uncorrected serum or plasma calcium lab value reported in EQRS.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure. Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure. Facility reports in ESRD Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure. The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure. Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure. Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure. Percentage of HCP who are up to date on their COVID-19 vaccination.

* We are proposing to update the ICH CAHPS clinical measure beginning with PY 2028, as discussed in section IV.C.2. of this proposed rule.

** We are proposing to remove the Facility Commitment to Health Equity reporting measure beginning with PY 2027, as discussed in section IV.B.1. of this proposed rule.

*** We are proposing to remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.B.2. of this proposed rule.

2. Proposal To Update the ICH CAHPS Clinical Measure Beginning With the PY 2028 ESRD QIP

a. Background

Section 1881(h)(2)(A)(ii) of the Act states that the Secretary shall specify, to the extent feasible, measures of patient satisfaction. Patients with ESRD are a vulnerable population. They are reliant on ESRD facilities for life-saving therapy, and they are often reluctant to express concerns about the care they receive from a variety of staff, both professional and non-professional. Patient-centered experience is an important measure of the quality of patient care, and it is a component of the CMS National Quality Strategy, which emphasizes patient-centered care by rating patient experience as a means for empowering patients and improving the quality of their care.

The ICH CAHPS Survey was developed to capture the experience of in-center hemodialysis patients. The ICH CAHPS measure was one of the foundational measures of the ESRD QIP measure set, initially as a reporting measure (76 FR 70269 through 70270) and then as a clinical measure beginning with PY 2018 (79 FR 66198 through 66200).

b. Proposed Survey and Measure Changes

ICH CAHPS Surveys are administered semiannually, and an eligible facility's score on the ICH CAHPS clinical measure is currently based on the three composite or multi-item measures (QDCCO, NCC, and Providing Information to Patients [PIP]) and three global ratings (ratings of nephrologists, dialysis center staff, and dialysis center), all of which are equally weighted. In recent years, commenters

have expressed concerns that patients may experience survey fatigue related to both the length of the survey and the frequency of being requested to participate in the survey twice a year. In addition, survey response rates continue to slowly decline, and it is believed that the length of the survey could be a contributing factor.

To address these concerns, we conducted a number of activities related to reducing the length of the current ICH CAHPS Survey. Based on psychometric analyses, discussions with a Technical Expert Panel of ESRD entities, survey experts, and large dialysis organizations, focus groups with dialysis patients, and discussions with the CAHPS Consortium, proposed revisions to the ICH CAHPS Survey used to calculate performance on the ICH CAHPS clinical measure include:

- Removal of four questions, which are unnecessary for the psychometric

¹⁴ <https://www.cms.gov/files/document/esrd-measures-manual-v100.pdf>.

¹⁵ In previous years, we referred to the consensus-based entity by corporate name. We have updated

this language to refer to the consensus-based entity more generally.

function of the Quality of Dialysis Center Care and Operations (QDCCO) multi-item measure:

++ Whether the dialysis center staff inserted needles with as little pain as possible,

++ whether dialysis center staff talked to patients about what they should eat and drink,

++ whether the dialysis center staff keep health information as private as possible, and

++ whether the patient felt the staff cared about them “as a person.”

- Removal of all six questions that make up the Nephrologists’ Communication and Caring (NCC) multi-item measure.

- Removal of the nephrologist rating question.

Additionally, to reduce the length of the ICH CAHPS Survey, we propose to update the ICH CAHPS Survey to include the following non-measure changes:

- Removal of two core questions not currently used in public reporting measures:

++ Whether the dialysis center staff asked about how kidney disease affects other parts of patient’s lives, and

++ whether patients made a complaint to Medicare or their State agencies.

- Removal of nine questions from the About You section and one question from the mail survey proxy series.

- Consolidation of the race and ethnicity questions into one question, as per OMB Statistical Policy Directive No. 15 requirements.¹⁶

c. Pre-Rulemaking Review Process and Measure Endorsement

As required under section 1890A of the Act, the Secretary must establish and follow a pre-rulemaking review process for selection of quality and efficiency measures, including for the ESRD QIP. The pre-rulemaking review process, which we refer to as Pre-Rulemaking Measure Review (PRMR), includes a review of measures published on the publicly available list of Measures Under Consideration by one of several committees convened by the consensus-based entity (CBE), with whom we contract in accordance with section 1890 of the Act, for the purpose of providing interested parties’ input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the ESRD QIP.

The revised ICH CAHPS Survey, including the revised QDCCO multi-item measure, was submitted to the 2024 Measures Under Consideration list (MUC2024–060) and underwent evaluation by the PRMR Hospital Committee. The PRMR Hospital Committee recommended the ICH CAHPS survey changes be implemented.¹⁷ The revised ICH CAHPS Survey was submitted to the CBE for endorsement through the Spring 2025 Partnership for Quality Measurement (PQM) Endorsement and Maintenance (E&M) process.¹⁸ The E&M process ensures measures submitted for endorsement are evidence-based, scientifically sound, safe and effective. The current ICH CAHPS Survey measure was endorsed by the CBE in Spring 2019. Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We have determined that the updates to the ICH CAHPS clinical measure are appropriately specified, and therefore the exception in section 1881(h)(2)(B)(ii) of the Act applies. We note that the ICH CAHPS measure remains an endorsed measure, and the updated ICH CAHPS measure, which only reduces the number of questions in the ICH CAHPS Survey, has been submitted to the CBE for endorsement. To ensure that the revised ICH CAHPS Survey is reflected in the updated ICH CAHPS clinical measure beginning with PY 2028, we are proposing to implement the revised ICH CAHPS Survey beginning with the CY 2026 Spring survey.

d. Impact To Measure Calculation and Public Reporting

ICH CAHPS Survey measure scores are calculated based on two rolling semiannual surveys and are published semiannually for all ICH facilities that meet reporting criteria. With the

proposed implementation of the revised survey, we are proposing to calculate the ICH CAHPS clinical measure based on the remaining multi-item measures—the revised QDCCO and PIP—and the remaining global ratings of the dialysis center staff and the dialysis center. In the calculation of the ICH CAHPS clinical measure, we are proposing that all of the measures, including the multi-item and global rating measures, would be weighed equally. The ICH CAHPS clinical measure would continue to be calculated using two rolling semiannual surveys and would be publicly reported for all eligible facilities with 30 or more completed surveys over the reporting period.

To determine what impact the changes to the survey measures would have on public reporting, CMS considered the nature of the changes. Psychometric and other analyses were performed on field test data and no major impact was found. We anticipate that the first Care Compare refresh in which publicly reported scores would be updated to include two semiannual periods using the revised survey would be October 2027 (2026 Spring and 2026 Fall Surveys). Because the April 2027 refresh would include a survey period that used the current survey (2025 Fall) and a survey period that used the revised survey (2026 Spring), we propose to reanalyze the 2025 Fall data without the NCC measure and rating and without the 4 dropped QDCCO measure questions, then combine the reanalyzed data with the 2026 Spring data for public reporting in April 2027. Therefore, we would not miss a refresh for ICH CAHPS data.

e. Survey Administration Changes

No survey administration changes are proposed with the new survey.

f. Case-Mix and Mode Adjustments

Prior to public reporting, ICH CAHPS Survey scores are adjusted for the effects of case-mix (patient-mix). Case-mix refers to characteristics of the patient that are not under control of the facility that may affect reports of in-center dialysis experiences. Case-mix adjustment is performed within each semiannual survey period after data cleaning. The current case-mix adjustment model includes the following variables: overall health, overall mental health, heart disease, deaf or serious difficulty hearing, blind or serious difficulty seeing, difficulty dressing or bathing, age, sex, education, does the patient speak a language other than English at home, whether someone helped complete the survey, and total years on dialysis. The model used and

¹⁶ OMB, The 2024 Statistical Policy Directive No. 15, March 2024. Available at <https://spd15revision.gov/content/spd15revision/en/2024-spd15.html>.

¹⁷ Partnership for Quality Measurement, PRMR 2024 MUC Final Recommendations Spreadsheet. Available at <https://p4qm.org/media/3891>.

¹⁸ Information about the Partnership for Quality Measurement E&M process is available at <https://p4qm.org/EM>.

adjustments are updated semiannually and are available on the ICH CAHPS website at https://ichcahps.org/Portals/0/PublicReporting/ICHCAHPS_PublicRptCoeffOct2024.pdf. Based on testing the revised survey in a field test, CMS reviewed the variables included in the case-mix adjustment models currently in use for the ICH CAHPS Survey to determine if any changes needed to be introduced along with the revised survey. Several questions that were included as original case-mix adjusters showed little impact on survey responses, so the questions were removed to shorten the survey instrument. Based on this and the case-mix analysis of the field test data, we propose that the new case-mix adjusters for the revised survey include overall health, overall mental health, age, sex, education, language survey was conducted in, whether someone helped complete the survey, total years on dialysis, and whether diabetes was primary cause of ESRD.

We note that, in addition to the proposed updates to the ICH CAHPS clinical measure in this proposed rule, we are also exploring additional ways to improve the ICH CAHPS measure. We are currently working on developing and testing a web with mail follow-up mode to provide facilities with alternate methods of survey administration, and we are also working on a modified survey to include questions that address the experience of care for patients on home dialysis modalities.

We welcome public comment on our proposal to update the ICH CAHPS clinical measure for the PY 2028 ESRD QIP and subsequent years.

3. Performance Standards for the PY 2028 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined

appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by sections 1881(h)(4)(B) and (C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277), as well as § 413.178(a)(1), (3), (7), and (12), for further information related to performance standards.

We continue to believe that our current policy of 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we would adopt CY 2026 as the performance period and CY 2024 as the baseline period for the PY 2028 ESRD QIP. In this proposed rule, we are estimating the performance standards for the PY 2028 clinical measures in Table 10 using data from CY 2023, which are the most recent data available. We intend to update these performance standards for all measures, using CY 2024 data, in the CY 2026 ESRD PPS final rule.

TABLE 10—PERFORMANCE STANDARDS FOR THE PREVIOUSLY FINALIZED AND PROPOSED UPDATED ESRD QIP CLINICAL MEASURES FOR PY 2028

Measure	Achievement threshold (15th percentile of national performance)	Median (50th percentile of national performance)	Benchmark (90th percentile of national performance)
Vascular Access Type (VAT):			
Long-Term Catheter Rate	18.35%	11.04%	4.69%
Kt/V Dialysis Adequacy Measure Topic:			
Adult Hemodialysis (HD) Kt/V	95.79%	98.34%	99.68%
Pediatric Hemodialysis (HD) Kt/V	81.25%	92.37%	100.00%
Adult Peritoneal Dialysis (PD) Kt/V	87.34%	94.85%	99.04%
Pediatric Peritoneal Dialysis (PD) Kt/V	66.49%	82.06%	95.18%
Standardized Readmission Ratio ^a	34.27	26.50	16.18
NHSN BSI	0.642	0.215	0
Standardized Hospitalization Ratio ^b	166.60	129.14	87.98
Standardized Transfusion Ratio ^b	48.29	26.19	8.46
PPPW	8.12%	16.73%	33.90%
Clinical Depression	88.21%	94.34%	100.00%
ICH CAHPS: Quality of Dialysis Center Care and Operations*	54.93%	63.89%	75.33%
ICH CAHPS: Providing Information to Patients	70.82%	77.29%	84.95%
ICH CAHPS: Overall Rating of Dialysis Center Staff	51.74%	64.96%	79.23%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.88%	68.62%	83.27%

* We are proposing to update the ICH CAHPS clinical measure beginning with PY 2028, as discussed in section IV.C.2. of this proposed rule.

^a Rate calculated as a percentage of hospital discharges.

^b Rate per 100 patient-years.

Data sources: VAT measure: 2023 EQRS; SRR, SHR, STaR: 2023 Medicare claims; Kt/V: 2023 EQRS and 2023 Medicare claims; NHSN: 2023 CDC; ICH CAHPS: CMS 2023; PPPW: 2023 EQRS and 2023 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2023 EQRS.

In addition, we summarize in Table 11 our requirements for successful

reporting on our previously finalized and proposed updated reporting

measures for the PY 2027 and PY 2028 ESRD QIP.

TABLE 11—REQUIREMENTS FOR SUCCESSFUL REPORTING OF ESRD QIP REPORTING MEASURES FOR PY 2027 AND PY 2028

Measure	Reporting frequency	Data elements
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: ○ physician, ○ nurse, ○ advanced registered nurse practitioner (ARNP), ○ physician assistant (PA), ○ pharmacist, or ○ pharmacy technician personnel. • Name of eligible professional.
Hypercalcemia	Monthly	Total uncorrected serum or plasma calcium lab values
COVID–19 Vaccination Coverage Among HCP.	At least one week of data each month, submitted quarterly.	Cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who are up to date on their COVID–19 vaccination.

* We are proposing to remove the Facility Commitment to Health Equity reporting measure beginning with PY 2027, as discussed in section IV.B.1. of this proposed rule. We are also proposing to remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.B.2. of this proposed rule.

4. Eligibility Requirements for the PY 2028 ESRD QIP

In this proposed rule, we are not proposing to update eligibility

requirements as part of our proposal to update the ICH CAHPS clinical measure, as discussed in section IV.C.2. of this proposed rule. Our previously

finalized minimum eligibility requirements are described in Table 12.

TABLE 12—PREVIOUSLY FINALIZED ELIGIBILITY REQUIREMENTS FOR SCORING ON ESRD QIP MEASURES BEGINNING WITH PY 2028

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Dialysis Adequacy Measure Topic: Adult HD Kt/V (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Kt/V Dialysis Adequacy Measure Topic: Pediatric HD Kt/V (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Kt/V Dialysis Adequacy Measure Topic: Adult PD Kt/V (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Kt/V Dialysis Adequacy Measure Topic: Pediatric PD Kt/V (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
VAT: Long-term Catheter Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Hypercalcemia (Reporting)	11 qualifying patients.	Before September 1 of the performance period that applies to the program year.	N/A.
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11–25 qualifying patients.
SRR (Clinical)	11 index discharges	N/A	11–41 index discharges.
STrR (Clinical)	10 patient-years at risk	N/A	10–21 patient-years at risk.
SHR (Clinical)	5 patient-years at risk	N/A	5–14 patient-years at risk.
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	Before October 1 prior to the performance period that applies to the program year.	N/A.
Depression Screening and Follow-Up (Clinical).	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	11–25 qualifying patients.
MedRec (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A.
PPPW (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.
COVID–19 Vaccination Coverage Among HCP (Reporting).	N/A	Before September 1 of the performance period that applies to the program year.	N/A.

* We are proposing to remove the Facility Commitment to Health Equity reporting measure beginning with PY 2027, as discussed in section IV.B.1. of this proposed rule. We are also proposing to remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.B.2. of this proposed rule.

5. Payment Reduction Scale for the PY 2028 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with its performance under the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at § 413.178(a)(8).

Under § 413.177(a), we implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility’s TPS falls below the mTPS, up to a maximum reduction of 2 percent. For PY 2028, we estimate using available data that a facility must meet or exceed an mTPS of 56 to avoid a payment reduction. The estimated payment reduction scale for PY 2028 based on the most recently available data is described in Table 13. We note that the mTPS estimated in this proposed rule is based on data from CY 2023 instead of the PY 2028 baseline period (CY 2024) because CY 2024 data are not yet available. We will update and finalize the mTPS and associated payment reduction ranges for PY 2028, using CY 2024 data, in the CY 2026 ESRD PPS final rule.

TABLE 13—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2028 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–56	0
55–46	0.5
45–36	1.0
35–26	1.5
25–0	2.0

D. Requests for Information (RFIs) on Topics Relevant to ESRD QIP

As discussed in the following sections of this proposed rule, we are requesting information on topics to inform future revisions to the ESRD QIP. First, we are requesting information on the current state of health information technology (IT) use in dialysis facilities, including electronic health records, to further ongoing efforts to facilitate successful adoption and integration of Fast Healthcare Interoperability Resources® (FHIR®), FHIR-based technologies and standardized data for patient assessment instruments. We are also requesting information regarding potential measurement concepts that could be developed into ESRD QIP measures in the future.

Note that each of these sections is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), these general solicitations are exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency’s full consideration, are not generally considered information collections and therefore not subject to the PRA.

Respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; they do not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. These RFIs do not commit the United States Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the United States Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party’s expense. Not responding to these RFIs does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor these RFI announcements for additional information pertaining to this request. Note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the United States Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the United States Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which

reimbursement would be required or sought. All submissions become United States Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

1. Request for Public Comment on Advancing Digital Quality Measurement in the ESRD QIP

a. Background

We are committed to improving healthcare quality through measurement, transparency, and public reporting of quality data, and to enhancing healthcare data exchange by promoting the adoption of interoperable health information technology (IT) that enables information exchange through the use of FHIR® standards. Proposing to require the use of such technology within the ESRD QIP in the future could potentially enable greater care coordination and information sharing, which is essential for delivering high-quality, efficient care and better outcomes at a lower cost. In the CY 2022 ESRD PPS final rule, we outlined several HHS initiatives aimed at promoting the adoption of interoperable health information technology (IT) and facilitating nationwide health information exchange (86 FR 61941 through 61945). Further, to inform our digital strategy, we sought and received feedback, described in the CY 2022 ESRD PPS final rule, on our intent to explore the use of FHIR-based standards to exchange clinical information through application programming interfaces (APIs), enabling quality data submission to CMS through EQRS, and to work with healthcare standards organizations to ensure their standards support our assessment tools (86 FR 61941 through 61948).

We are considering opportunities to advance FHIR-based reporting of patient assessment data for the submission of ESRD QIP data. Our objective is to explore how dialysis facilities typically integrate health IT with varying complexity into existing systems and how this affects facility workflows. We seek to identify the challenges and/or opportunities that may arise during this integration, and determine the support needed to complete and submit the data in ways that protect and enhance care delivery.

Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

b. Solicitation for Comment

We seek feedback on the current state of health IT use, including EHRs, in ESRD facilities:

- What health IT does your facility use to maintain patient records, and are these health IT certified by the Assistant Secretary for Technology Policy (ASTP) and the Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP)? If your facility uses EHRs that are not certified by ONC, please specify. Does your facility maintain any patient records outside of these electronic systems? If so, is the data organized in a structured format, using codes and recognized standards, that can be exchanged with other systems?

- Does your facility submit patient assessment data to CMS through your current health IT system? If a third-party intermediary is used to report data, what type of intermediary service is used? How does your facility currently exchange health information with other healthcare providers or systems, specifically between facilities and other provider types? What are the challenges?

- Are there any challenges with your current electronic devices that hinder your ability to achieve interoperability, such as collecting, storing, sharing, or submitting data? Please describe any specific issues you encounter. Does limited internet or lack of internet connectivity impact your ability to exchange data with other healthcare providers, including community-based care services, or your ability to submit assessment data to CMS? Please specify.

- What challenges or barriers does your facility encounter when submitting quality data to CMS as part of the ESRD QIP? What opportunities or factors could improve your facility's successful data submission to CMS?

- What types of technical support, guidance, workforce trainings, and/or other resources would be most beneficial for the implementation of FHIR-based technology in your facility for the submission of the data to CMS? How could these resources be designed to minimize complexity and burden on healthcare providers while ensuring the protection of patient care and maintaining staffing capacities during implementation? How could Quality Improvement Organizations (QIOs) or other entities enhance this support?

- How do you anticipate the adoption of FHIR-based standards for reporting patient assessment data could impact provider workflows? What impact, if any, do you anticipate it will have on quality of care?

- Does your facility have any experience using technology that conforms to a version or versions of the United States Core Data for Interoperability (USCDI) standard for data? Is your facility using technology that utilizes APIs based on the FHIR® standard for electronic data exchange? If so, with whom are you exchanging data using the FHIR® standard and for what purpose(s)? Has your facility used a SMART on FHIR®¹⁹ application? If so, was the SMART on FHIR® application integrated with your EHR? Additionally, what benefits or challenges have you experienced with the implementation of FHIR® using APIs or USCDI?

- What might encourage your facility and/or vendors to participate in testing to explore options for transmission of assessments, for example testing the transmission of a FHIR-based assessment to CMS?

- How could the Trusted Exchange Framework and Common Agreement™ (TEFCA™) support CMS quality programs' adoption of FHIR-based assessment submissions consistent with the FHIR® Roadmap (available here <https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/>)? How might patient assessment data hold secondary uses for treatment or other TEFCA exchange purposes?

- What other information should we consider, that could facilitate successful adoption and integration of FHIR-based technologies and standardized data for patient assessment instruments? We invite any feedback, suggestions, best practices, or success stories related to the implementation of these technologies.

2. Request for Information on Measure Concepts Under Consideration for Future Years

The first concept about which we are seeking feedback is for a measure of interoperability with a focus on systems readiness and capabilities in the dialysis facility setting. The Public Health Service Act defines “interoperability” in part, and with respect to health information technology, as health information technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without requiring special efforts by the user.²⁰ The definition further notes that interoperability of health information technology allows providers and patients to access, exchange, and use electronically accessible health

information for authorized use under applicable State or Federal law. To achieve interoperability, a system should adopt and optimize electronic health records (EHRs) and health information exchange services.²¹ We request input and comment on approaches to assessing interoperability in the dialysis facility setting, for instance, measures that address or evaluate the level of readiness for interoperable data exchange, or measures that evaluate the ability of data systems to securely share information across the entire spectrum of care with special consideration of exchange of information between dialysis facilities and both inpatient (including transplant centers) and outpatient facilities and providers.

A second concept about which we are seeking feedback is for a measure of well-being. Well-being is a comprehensive approach to disease prevention and health promotion, as it integrates mental, social, and physical health while emphasizing preventative care to proactively address potential health issues.²² This comprehensive approach emphasizes person-centered care by promoting well-being of patients and their care partners. We are seeking comment on tools and measures that assess for overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, and fulfillment. We would like to receive input and comment on the applicability of tools and constructs that assess for the integration of complementary and integrative health, skill building, and self-care. Please provide feedback on the relevant aspects of well-being for the ESRD QIP.

A third concept about which we are seeking feedback is for measures of nutrition. Assessment for nutritional status may include various strategies, guidelines, and practices designed to promote healthy eating habits and ensure individuals receive the necessary nutrients for maintaining health, growth, and overall well-being. Nutrition is a complex concept for patients with ESRD who may also have dietary restrictions, fluid restrictions, and/or frailty; however, adequate nutrition and nutritional support are important for overall health in this population. Maximizing nutrition can

²¹ The Office of the National Coordinator for Health Information Technology. “The Path to Interoperability”. September 2013. Available at https://www.healthit.gov/sites/default/files/factsheets/nc_interoperabilityfactsheet.pdf.

²² Well-Being Concepts. CDC Archives. <https://archive.cdc.gov/#/details?url=https://www.cdc.gov/hrqol/wellbeing.htm>.

¹⁹ <https://smarthealthit.org/>.

²⁰ 42 U.S.C. 300jj(9).

assist with dialysis treatment tolerance, improvement in comorbid conditions, and readiness for kidney transplant, if desired. We are seeking feedback on tools and frameworks that promote healthy eating habits and nutrition for patients requiring dialysis. Please provide feedback on the relevant aspects of nutrition for the ESRD QIP.

A fourth concept about which we are seeking feedback is for measures of physical activity. Although dialysis therapy presents barriers to physical activity for many patients including physical, structural, psychological, and practical barriers, physical activity and purposeful movement are critical for patients on dialysis. Physical activity can improve physical functioning, sleep, and well-being for patients on dialysis as well as potentially impact comorbid conditions. We are seeking feedback on all relevant aspects of physical activity for the ESRD QIP.

Finally, we are seeking feedback on measures related to chronic kidney disease (CKD) that would encourage early detection, early and appropriate treatment, and delay of progression to ESRD. The prevention or significant delay in the need for dialysis would profoundly impact patients. Please provide feedback on all relevant aspects of CKD prevention and treatment in all settings.

We welcome public comment on the future measure concepts under consideration for the ESRD QIP described in Table 14.

TABLE 14—FUTURE MEASURE CONCEPTS UNDER CONSIDERATION FOR THE ESRD QIP

ESRD QIP quality measure concepts
Interoperability.
Well-being.
Nutrition.
Physical Activity.

While we will not be responding to specific comments in response to this RFI in the CY 2026 ESRD PPS final rule, we intend to use this input to inform our future measure development efforts.

V. End-Stage Renal Disease Treatment Choices (ETC) Model

A. Background

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of these programs. The purpose of the ETC

Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support ESRD Beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD Beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

The ETC Model is a mandatory payment model. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas—a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to be included in the ETC Model, as well as HRRs with at least 20 percent of ZIP codes™ located in Maryland.²³ CMS excludes all United States Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD PPS on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning January 1, 2021, and ending December 31, 2023.

The second payment adjustment under the ETC Model is the Performance Payment Adjustment (PPA). For the PPA, we assess ETC Participants’ home dialysis rates and transplant rates during a Measurement Year (MY), which includes 12 months of performance data. Each MY has a corresponding PPA Period—a 6-month period that begins 6 months after the conclusion of the MY. We adjust certain

payments for ETC Participants during the PPA Period based on the ETC Participant’s home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY.

Based on an ETC Participant’s achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant’s improvement in relation to their own home dialysis rate and transplant rate during the Benchmark Year, we would make an upward or downward adjustment to certain payments to the ETC Participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the Model. These PPAs apply to claims with claim service dates beginning July 1, 2022, and ending June 30, 2027.

CMS has modified the ETC Model several times. In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We adjusted the calculation of the home dialysis rate (86 FR 61951 through 61955) and the transplant rate (86 FR 61955 through 61959) and updated the methodology for attributing Pre-emptive LDT Beneficiaries (86 FR 61950 through 61951). We changed the achievement benchmarking and scoring methodology (86 FR 61959 through 61968), as well as the improvement benchmarking and scoring methodology (86 FR 61968 through 61971). We specified the method and requirements for sharing performance data with ETC Participants (86 FR 61971 through 61984). We also made a number of updates and clarifications to the kidney disease patient education services waivers and made certain related flexibilities available to ETC Participants (86 FR 61984 through 61994). In the CY 2023 ESRD PPS final rule (87 FR 67136) we finalized further changes to the ETC Model. We updated the PPA achievement scoring methodology beginning in the fifth MY of the ETC Model, which began on January 1, 2023 (87 FR 67277 through 67278). We also clarified requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model’s Medicare program waivers (87 FR 67278 through 67280) and finalized our intent to publish participant-level model performance information to the public (87 FR 67280). In the CY 2024 ESRD PPS final rule (88 FR 76344) we finalized a policy whereby an ETC Participant may seek administrative review of a targeted review determination provided by CMS.

²³ ZIP code™ is a trademark of the United States Postal Service.

In the CY 2025 ESRD PPS final rule (89 FR 89084) we finalized a modification to the definition of ESRD Beneficiary at 42 CFR 512.310 as that definition is used for the purposes of attributing beneficiaries to the ETC Model.

B. Provisions of the Proposed Rule

1. Termination of the ETC Model

In this proposed rule, we are proposing to terminate the ETC Model as of December 31, 2025. Section 1115A of the Act gives the Secretary the authority to terminate Innovation Center models. Specifically, section 1115A(b)(3)(B) of the Act states that “The Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services, with respect to program spending under the applicable title, certifies), after testing has begun, that the model is expected to—improve the quality of care (as determined by the Administrator of the Centers for Medicare & Medicaid Services) without increasing spending under the applicable title; reduce spending under the applicable title without reducing the quality of care; or improve the quality of care and reduce spending. Such termination may occur at any time after such testing has begun and before completion of the testing.”²⁴

ETC Model performance since 2021 has not been shown to enhance the quality-of-care ETC regions on the key model measures of home dialysis modalities, transplant waitlisting, and living donor transplantation. The second Annual Evaluation Report (AR2) examined impacts of the ETC Model during calendar years CYs 2021 and 2022, which correspond to the first three model years (MYs) of the model. While AR2 showed home dialysis use continued to grow nationally, there was no evidence of faster growth within selected geographic areas relative to the comparison group of geographic areas not selected for the ETC Model. Further, for transplant-related measures, AR2 showed no evidence of a change in waitlisting rates in ETC areas relative to comparison areas. Increased rates of both home dialysis training and transplantation were only evident in CY 2021 and were not sustained in CY 2022.²⁵

Also of note is that the ETC Model has not reduced Medicare expenditures throughout the duration of the ETC model and in fact has increased expenditures. The AR2 evaluation preliminarily showed that net Medicare payments increased by \$56 million over the course of the model. The model was initially projected to show savings by decreasing payments for participants such that they would likely not be able to hit the required thresholds for performance in the ETC Model. However, due to stronger than expected increases in rates of home dialysis caused by factors other than the model and the effects of the improvement scoring methodology, managing clinicians and ESRD facilities performed better than expected and have received a net increase in payments.²⁶

CMS issued an RFI in the CY 2025 ESRD PPS final rule (89 FR 89084) seeking comments about potential future policies that CMS could undertake to increase home dialysis rates and better support beneficiaries. Many of these suggestions that we received from the RFI are actively being tested in the Kidney Care Choices (KCC) Model, such as the Kidney Disease Education (KDE) benefit waiver, home dialysis quality measures focused on retention and optimal starts, efforts to increase transplantation, and a focus on home dialysis primarily through peritoneal dialysis (PD) as the dominant home dialysis modality.

Results of the PY 2022 evaluation for the KCC Model demonstrate promising strides towards the aforementioned shared goals with the ETC model, and more specifically, a statistically significant increase in home dialysis rates for aligned beneficiaries in aggregate. Specifically, KCC participants increased the proportion of patients receiving PD in a given month by 2.3 percentage points. This statistically significant relative increase represents about 26 percent of the pre-KCC mean. Additionally, Comprehensive Kidney Care Contracting (CKCC) model participants increased the proportion of patients receiving PD in a given month by 0.74 percentage points. This statistically significant relative increase represents about 8 percent of the pre-KCC mean.²⁷

evaluation report (Contract No. 75FCMC19D0096). The Lewin Group. <https://www.cms.gov/priorities/innovation/data-and-reports/2024/etc-2nd-eval-rpt/>.

²⁶ Ibid.

²⁷ Negrusa, B., Wiens, J., Ullman, D., Dahlerus, C., Hirth, R., Maillet, A., Strubler, D., Pinson, R., Mindock, M., Bacon, K., Kappes, A., Johann, A., Vomacka, B., Schaefer, M.B., Segal, J., Shahinian, V., Li, Y., Shearon, T., Ashby, V., Nahra, T.,

Given these factors, we are proposing to terminate the ETC model as of December 31, 2025. Specifically, we are proposing to revise the duration of the ETC Model at § 512.320 from claims with claim service dates beginning on or after January 1, 2021, and ending on or before June 30, 2027, to claims with claim service dates beginning on or after January 1, 2021, and ending on or before December 31, 2025. We seek public comment on our proposal to modify the duration of the ETC Model § 512.320.

Additionally, we are proposing to modify our regulation at §§ 512.355(a) through (b) to specify that the final Measurement Year (MY) ends on December 31, 2024, and the final Performance Payment Adjustment (PPA) ends December 31, 2025. This proposal would make MY7 and PPA 7 the last MY and PPA of the ETC Model. Therefore, we also propose to modify Table 1 to paragraph (c)—ETC Model Schedule of Measurement Years and PPA Periods at § 512.355 to eliminate the entries for MY 8 through MY 10. We seek public comment on our proposal to modify our regulation at §§ 512.355(a) through (c) to make MY7 and PPA7 the final MY and PPA of the ETC Model.

In order to align the remaining regulation text with our proposal to terminate the model after MY 7, we propose to modify §§ 512.360(c)(2)(iii), 512.365(b)(1)(ii), 512.365(c)(1)(i)(A), 512.365(c)(1)(ii), 512.365 (c)(2)(i)(A), 512.365 (c)(2)(ii)(A)(1) and 512.365 (c)(2)(ii)(A)(2) to remove references to MYs 8 through 10, and change any references to the last MY of the ETC model to reference MY7. We seek public comment on these proposals.

Also, for the reasons listed previously, we propose to modify §§ 512.370(b) introductory text, Table 1 to paragraph (b)(1) of 512.370, 512.370(b)(2), 512.370 (b)(3), 512.370 (c), 512.370(c)(1)(v), and 512.370(d)(2) to remove references to MYs 8 through 10, and change any references to the last MY of the ETC model to reference MY7. Finally, we propose to modify Table 1 to § 512.380—Facility PPA Amounts and Schedule, and Table 2 to § 512.380 to remove references to MYs 8 through 10, and § 512.390(b) to clarify when we propose to stop data sharing and the sharing of reports. We seek public comment on this proposal.

Given this proposed termination, we also plan to stop any data sharing and reports as of November 30, 2025, which would include any information about

Gunden, J., Wang, M., Garcia, A., & Yaldo, A. (2024). *Kidney care choices (KCC) model: First annual evaluation report, performance year 2022* (Contract No. 75FCMC19D0096). The Lewin Group. <https://www.cms.gov/kcc-model-eval-ann-rpt-1>.

²⁴ 42 U.S.C. 1315a.

²⁵ Negrusa, B., Wiens, J., Ullman, D., Turenne, M., Mukhopadhyay, P., Young, E., Mandell, R., Stanik, C., Pozniak, A., Goyat, R., Ji, N., Martin, A., Wang, D., Wiseman, J., Tian, S., Milkovich, K., Dahlerus, C., & Hirth, R. (2024). *End-stage renal disease treatment choices (ETC) model: Second annual*

model performance in MYs 7 through 10. This action accommodates the abbreviated project schedule of our implementation contractor in alignment with the early termination of the model on December 31, 2025. Two evaluation reports have been completed and made public. The First Annual Evaluation Report was published in July 2023 and pertained to the first year of the model (CY 2021), Measurement Years (MYs) 1 and 2. The Second Annual Evaluation Report was published on January 2024 and pertained to CY 2021 and CY 2022, which corresponds to MYs 1–3. The Third Annual Evaluation Report will be completed and is expected to be made public in the second half of 2025. This evaluation report will cover CYs 2021–2023 and pertain to MYs 1–6. We anticipate that there will be a Fourth Annual Evaluation Report expected to be made public after the end of the ETC model. This evaluation report will cover CYs 2021–2025 and pertain to MYs 1–7. We seek public comment on this proposal.

2. Discussion of Hurricane Helene and the ETC Model

Hurricane Helene hit western North Carolina on October 1 and 2, 2024. The hurricane affected a factory operated by Baxter International in Marion, NC that produces approximately 60 percent of the nation's supply of IV fluids and peritoneal dialysis solutions. Baxter stopped providing PD supplies for new starts after October 1, 2024, and it took until February 17, 2025, before all of their manufacturing lines returned to pre-hurricane production levels. Even with that announcement, they stated that “allocations remain necessary, and we will continue to provide related updates for our customers directly”, suggesting continued disruptions.²⁸ The final statement released from Baxter on this issue dated May 13, 2025, focused on the complete restoration of inventory levels for IV Solutions only. Interested parties with additional inquiries regarding the production of PD solutions were directed to Vantive.²⁹

Given the potential impact of Hurricane Helene on home dialysis, we considered adjusting the schedule and methodologies for the PPA. The impacts of Hurricane Helene could disrupt performance metrics for participants for MY 7, 8, and 9 (CY 2024 Q3 and Q4

through CY 2025 Q1 and Q2) and Benchmark Years (BY) 7, 8, and 9. A decrease in home dialysis for the PD modality in these time periods would begin to affect model performance payment adjustments to claims in July 2025. For the PPA, CMS assesses ETC Participants' home dialysis rate and transplant rate during an MY which includes 12 months of performance data. Some MYs overlap with the previous MY and the subsequent MY for a period of 6 months. Each MY has a corresponding PPA Period—a 6-month period which begins 6 months after the conclusion of the MY. CMS adjusts certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate. Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to its own home dialysis rate and transplant rate during the Benchmark Year, we make an upward or downward adjustment to certain payments to the ETC Participant.

As an alternative considered, we considered proposing that no upward or downward adjustments would be made for MY7 and PPA7 prior to the proposed termination of the model. Due to the timing of the publication of this proposed rule, changing the payment adjustments would be retroactive. However, initial research by the CMS contractor did not show a statistically significant change in home dialysis rates among participants and non participants for ETC Participant performance during October to December of 2024 when compared to January to September 2024. As such, we determined that proposing to eliminate the performance adjustments in the ETC Model for PPA 7 is unnecessary.

As part of this alternative that we considered to our proposal, we also recognize that Section 1871(e) of the Act lays out the principle that substantive changes in regulations shall not be applied retroactively unless the Secretary determines that either such retroactive application is necessary to comply with statutory requirements or failure to apply the change retroactively would be contrary to the public interest. If we receive comments providing significant empirical evidence of overwhelming negative effects of the supply shortage on the administration of home dialysis, implementing PPA 7 adjustments as currently written may not serve the public interest. We have heard anecdotal evidence that the

Baxter supply shortages starting October 1 could have reduced home dialysis participation rates, making it difficult for participants to meet their performance benchmarks. This was not reflected in our data analysis, but we are open to seeing data from participants that could adjust our proposal. Without CMS intervention, this could result in negative payment adjustments starting July 1, 2025, which could hurt the ability of managing clinicians and ESRD facilities to continue to serve patients. If payments are cut due to circumstances out of ESRD facilities and Managing Clinician's control, it could hurt beneficiary access or affect the quality of care received by beneficiaries.

We seek public comment on our proposal to make no changes to the schedule and methodologies for the PPA due to Hurricane Helene. We also seek comment on the alternative we considered of making no upward or downward adjustments for MY7 and PPA7 and applying that policy retroactively.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management & 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 comment on the following issues:

- The need for information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ESRD QIP—Wage Estimates

We refer readers to the CY 2025 ESRD PPS final rule for information regarding previously used wage estimates and resulting information collection burden calculations (89 FR 89194 through 89195). To derive wage estimates in this proposed rule, we used data from the United States Bureau of Labor Statistics'

²⁸ Baxter International Inc. (2025, February 17). *Hurricane Helene updates*. Baxter. <https://www.baxter.com/baxter-newsroom/hurricane-helene-updates>.

²⁹ Baxter International Inc. (2025, May 13). *Hurricane Helene updates*. Baxter. <https://www.baxter.com/baxter-newsroom/hurricane-helene-updates>.

May 2024 National Occupational Employment and Wage Estimates for Medical Records Specialists, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the Centers for Disease Control and Prevention's (CDC's) NHSN, as well as compiling and submitting patient records for the purpose of data validation. When this analysis was conducted, the most recently available median hourly wage of a Medical Records Specialist was \$24.16 per hour.³⁰ We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. Using these assumptions, we estimated an hourly labor cost of \$48.32 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this wage estimate, along with updated facility and patient counts, to update our estimates for the total information collection burden in the ESRD QIP for PY 2027 and to estimate the total information collection burden in the ESRD QIP for PY 2028. We will update the information collection burden to reflect updated facility and patient counts, in the CY 2026 ESRD PPS final rule.

B. Estimated Burden Associated With the Data Validation Requirements for PY 2028

We refer readers to the CY 2025 ESRD PPS final rule for information regarding the estimated burden associated with data validation requirements for PY 2027 (89 FR 89195).

1. Estimated Burden Associated With EQRS Data Validation Requirements for PY 2028

In this proposed rule, using the most recently available data, we estimate that the aggregate cost of the EQRS data

validation for PY 2028 would be approximately \$36,240 (750 hours × \$48.32), or an annual total of approximately \$120.80 (\$36,240/300 facilities) per facility in the sample. The burden cost increase associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1289).

2. Estimated Burden Associated With NHSN Data Validation Requirements for PY 2028

In this proposed rule, we estimate that the aggregate cost of the NHSN data validation for PY 2028 would be approximately \$72,480 (1,500 hours × \$48.32), or a total of approximately \$241.60 (\$72,480/300 facilities) per facility in the sample. While the burden hours estimate would not change, the burden cost updates associated with these requirements will be submitted to OMB as a revision of the information collection request currently approved under OMB control number 0938–1340.

C. Estimated EQRS Reporting Requirements for PY 2027 and PY 2028

To estimate the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2025 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2027 ESRD QIP was approximately \$136.1 million for approximately 2,901,090 total burden hours (89 FR 89195). In that final rule, we stated that for PY 2027 there are 136 data elements for 511,957 patients across 7,695 facilities, for a total of 69,626,152 elements across all patients (136 data elements × 511,957 patients). At 2.5 minutes per element, we

estimated that this would yield approximately 377 hours per facility. Therefore, we stated that the PY 2027 burden associated with EQRS reporting requirements as finalized in the CY 2025 ESRD PPS final rule would be 2,901,090 hours (approximately 377 hours × 7,695 facilities). Using the May 2023 wage estimate for a Medical Records Specialist, we estimated that the PY 2027 total burden cost would be approximately \$136.1 million (2,901,090 hours × \$46.90).

We are proposing three measure removals that would affect the burden associated with EQRS reporting requirements beginning with PY 2027. We provide the updated burden estimate for PY 2027 to reflect the impact of these proposals if finalized, as well as to reflect the updated May 2024 wage estimate for a Medical Records Specialist, and provide additional detail in Table 15. We will update the information collection burden to reflect updated facility and patient counts in the CY 2026 ESRD PPS final rule. In this proposed rule, we estimated that the amount of time required to submit measure data to EQRS would be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. There are 121 data elements for 511,957 patients across 7,695 facilities, for a total of 61,946,797 elements across all patients (121 data elements × 511,957 patients). If the three measure removals are finalized as proposed, the total number of data elements would decrease by 7,679,355 data elements based on current patient and facility counts. At 2.5 minutes per element, this would yield approximately 335 hours per facility. Therefore, the updated PY 2027 burden would be 2,581,117 hours (approximately 335 hours × 7,695 facilities), reflecting a burden decrease of 319,973 hours from our previously finalized estimate for PY 2027. Using the Medical Records Specialist wage estimates available at this time, we estimate that the updated PY 2027 total burden cost would be approximately \$124.7 million (2,581,117 hours × \$48.32).

³⁰ <https://data.bls.gov/oesprofile/>.

TABLE 15—ESTIMATED REDUCTION IN BURDEN ASSOCIATED WITH REMOVAL OF THREE REPORTING MEASURES BEGINNING WITH THE PY 2027 ESRD QIP

Requirement	Per facility		All facilities	
	Change in annual burden hours	Change in annual cost	Change in annual burden hours	Change in annual cost
Proposal to Remove Facility Commitment to Health Equity Reporting Measure	– 13.86	– \$669.71	– 106,658	– \$5,153,714.56
Proposal to Remove Social Drivers of Health Reporting Measure	– 13.86	– 669.71	– 106,658	– 5,153,714.56
Proposal to Remove Screen Positive for Social Drivers of Health Reporting Measure	– 13.86	– 669.71	– 106,658	– 5,153,714.56
Total Change in Information Collection Burden Hours: – 319,973 Total Cost Estimate: Updated Hourly Wage (Varies) × Change in Burden Hours (– 319,973) = – \$15,461,095				

We provide the burden estimate for PY 2028 and will update the information collection burden to reflect updated facility and patient counts, in the CY 2026 ESRD PPS final rule. In this proposed rule, we estimated that the amount of time required to submit measure data to EQRS would be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. There are 121 data elements for 511,957 patients across 7,695 facilities, for a total of 61,946,797 elements (121 data elements × 511,957 patients). At 2.5 minutes per element, this would yield approximately 335 hours per facility. Therefore, the PY 2028 burden would be 2,581,117 hours (approximately 335 hours × 7,695 facilities). Using the Medical Records Specialist wage

estimates available at this time, we estimate that the PY 2028 total burden cost would be approximately \$124.7 million (2,581,117 hours × \$48.32).

We intend to re-calculate the burden estimates for PY 2027 and PY 2028, using updated estimates of the total number of ESRD facilities, the total number of patients nationally, as well as a refined estimate of the number of hours needed to complete data entry for EQRS reporting in the CY 2026 ESRD PPS final rule. The information collection request currently approved under the OMB control number 0938–1289 will be revised and submitted to OMB for approval.

D. Estimated ICH CAHPS Reporting Requirements for PY 2028

The information collection request currently approved under OMB control

number 0938–0926 for the ICH CAHPS Survey is being revised and submitted to OMB for approval. As we are proposing a reduction of the ICH CAHPS survey from 62 to 39 questions, the survey length is decreasing from 16 to 12 minutes as the time for patients to complete each question ranges from 15 to 18 seconds on average. Although the average number sampled has increased in the information collection request currently approved under OMB control number 0938–0926 being submitted as part of this rule, the hour burden has decreased from 51,300 in the previous projection to 41,500 due to a reduction in the survey length, as described in Table 16. The costs will decrease from \$3,628,962 to \$2,973,890 which is a savings of \$655,072 annually.

TABLE 16—ESTIMATED REDUCTION IN BURDEN ASSOCIATED WITH PROPOSED UPDATES TO ICH CAHPS SURVEY BEGINNING WITH THE PY 2028 ESRD QIP

Requirement	Per dialysis facility		All dialysis facilities	
	Estimated change in annual burden hours	Estimated change in annual cost	Estimated change in annual burden hours	Estimated change in annual cost
Proposed update to ICH CAHPS Survey	– 1.4	– \$93.58	– 9,800	– \$655,072

Although we are also proposing changes to the ICH CAHPS clinical measure in this proposed rule that will reduce the burden associated with completing the ICH CAHPS survey, we do not anticipate that any of these proposed updates to the ICH CAHPS clinical measure would affect the facility reporting burden we have estimated for EQRS reporting requirements for PY 2028.

E. ESRD Treatment Choices Model

Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the ETC

Model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA do not apply to the testing and evaluation of Innovation Center models or to the expansion of such models. If you comment on this information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the ADDRESSES section of this proposed rule.

Comments must be received by the date and time specified in the DATES section of this rule.

VII. 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

VIII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD PPS

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Affordable Care Act (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRDB market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule proposes routine updates to the payment rate for renal dialysis services furnished by ESRD facilities and proposed policy changes to the ESRD PPS for CY 2026, including proposed updates to our ESRD PPS wage index, outlier threshold, TPNIES offset, and post-TDAPA add-on payment amounts to reflect the latest available data for Korsuva® and DefenCath®. We are also proposing a new payment adjustment to account for higher non-labor costs in certain non-contiguous States and territories, a proposed change to the timeframe for TDAPA eligibility. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2026 for renal dialysis services furnished to ESRD beneficiaries.

2. AKI

This rule proposes updates to the payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2026 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires CMS to reduce the payments otherwise made to a facility under the ESRD PPS for a year by up to 2 percent if the facility does not satisfy the requirements of the ESRD QIP for that year. This rule proposes updates for the ESRD QIP, which would remove the Facility Commitment to Health Equity reporting measure beginning with PY 2027, remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers

of Health reporting measure beginning with PY 2027, as well as update the ICH CAHPS clinical measure by reducing the number of questions on the ICH CAHPS Survey beginning with PY 2028.

4. ETC Model

The ETC Model is a mandatory Medicare payment model tested under the authority of section 1115A of the Act, which authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs.

This rule proposes to terminate the ETC Model due to a lack of statistically significant results. As described in detail in section V.B. of this proposed rule, we believe it is necessary, for the purposes of accuracy, to adopt this change to the ETC Model.

B. Overall Impact Analysis

We have examined the impacts of this rule as required by Executive Order 12866, “Regulatory Planning and Review”; Executive Order 13132, “Federalism”; Executive Order 13563, “Improving Regulation and Regulatory Review”; Executive Order 14192, “Unleashing Prosperity Through Deregulation”; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President’s priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of Executive Order 12866. Based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a Regulatory Impact Analysis that presents the costs and benefits of the rulemaking to the best of our ability.

1. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately \$160 million in Medicare payments to ESRD facilities in CY 2026. This includes \$160 million associated with the proposed payment rate updates, the updated post-TDAPA add-on payment adjustment amounts, and the continuation of the approved TDAPA as identified in Table 17. In addition, this amount includes, but is not impacted by, any budget neutral proposals for CY 2026 such as the routine updates to the ESRD PPS wage index and the new proposed non-contiguous areas payment adjustment (NAPA). In addition, for public awareness, we estimate that the proposed CY 2026 post-TDAPA add-on payment adjustments would total approximately \$27 million, an increase from around \$13 million in CY 2025. For CY 2026 we estimate TDAPA payments for drugs and biological products other than phosphate binders would total approximately \$70 million, an increase from around \$30 million in CY 2025.

2. AKI

We estimate that the proposed updates to the AKI dialysis payment rate would result in an increase of approximately \$1 million in Medicare payments to ESRD facilities in CY 2026.

3. ESRD QIP

We estimate that, as a result of our previously finalized policies and the policies we are proposing in this proposed rule, the updated ESRD QIP would result in \$22.1 million in estimated payment reductions across all facilities for PY 2027. Additionally, we estimate that, as a result of our previously finalized policies and the policies we are proposing in this proposed rule, the updated ESRD QIP would result in \$18.4 million in estimated payment reductions across all facilities for PY 2028.

4. ETC Model

We estimate that terminating the ETC Model on December 31, 2025, would

have a net impact of \$1 million in savings to Medicare due to not making performance payment adjustments (PPAs) during PPA8 through PPA10, which correspond with the remaining 18 months of the performance period (January 1, 2026–June 30, 2027).

5. Summary of Impacts

We estimate that the combined impact of the policies proposed in this rule on payments for CY 2026 is \$160 million based on the estimates of the updated ESRD PPS and the AKI dialysis payment rates. We estimate the impacts of the ESRD QIP for PY 2027 to be \$124.7 million in information collection burden and \$22.1 million in estimated payment reductions across all facilities. Additionally, we estimate the impacts of the ESRD QIP for PY 2028 to be \$124.7 million in information collection burden and \$18.4 million in estimated payment reductions across all facilities.

C. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this proposed rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this proposed rule.

1. Benefits

Under the CY 2026 ESRD PPS and AKI proposed payment, ESRD facilities would continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective Medicare payments to ESRD facilities will enhance the efficiency of the Medicare program. Additionally, we expect that updating the Medicare ESRD PPS base rate and rate for AKI treatments furnished by ESRD facilities by 1.9 percent based on the proposed CY 2026 ESRDB market basket percentage increase of 2.7 percent reduced by the proposed CY 2026 productivity adjustment of 0.8 percentage point would improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. We estimate that overall payments under the ESRD PPS would increase by 1.9 percent as a result of the proposed policies in this rule.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this proposed rule regarding ESRD PPS and AKI rates-setting would create

additional cost or burden to ESRD facilities.

b. ESRD QIP

We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for EQRS data validation (previously known as the CROWNWeb validation study) or NHSN data validation. Although we do not anticipate that the proposals regarding ESRD QIP would create additional cost or burden to ESRD facilities for PY 2027 or PY 2028, we intend to update the estimated costs associated with the information collection requirements under the ESRD QIP in the CY 2026 ESRD PPS final rule, with updated estimates of the total number of ESRD facilities, the total number of patients nationally, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting.

3. Transfers

We estimate that the proposed updates to the ESRD PPS and AKI dialysis payment rates would result in a total increase of approximately \$160 million in Medicare payments to ESRD facilities in CY 2026, which includes the amount associated with proposed updates to the outlier threshold amounts, the proposed NAPA, and proposed updates to the ESRD wage index. This estimate includes an increase of approximately \$1 million in Medicare payments to ESRD facilities in CY 2026 due to the updates to the AKI dialysis payment rate, of which approximately 20 percent is increased beneficiary coinsurance payments. We estimate approximately \$130 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately \$30 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary coinsurance payments because of this proposed rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this ESRD PPS 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 ESRD PPS proposed rule, we assume that the total number of unique commenters on last year's ESRD PPS proposed rule, which was 191 for the CY 2025 ESRD PPS proposed rule, is equal to the number of individual reviewers of this proposed rule. We acknowledge that this assumption may

understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters reviewed last year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the CY 2025 ESRD PPS proposed rule. For these reasons we determined that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We used a similar methodology for calculating the regulatory review costs in the CY 2025 ESRD PPS proposed rule. We welcomed any comments on the approach in estimating the number of entities which would review that proposed rule and did not receive any direct responses.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of this proposed rule. We seek comments on this assumption.

Using the BLS OEWS May 2024 National, cross-industry mean hourly wage information for medical and health service managers (SOC 11–9111), we estimate that the cost of reviewing this rule is \$132.44 (\$66.22 * 2) per hour, including overhead and fringe benefits³¹ (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 100 minutes (1.67 hours) for the staff to review half of this proposed rule, which has a total of approximately 50,000 words. For each entity that reviews the rule, the estimated cost is \$221.17 (1.67 hours × \$132.44). Therefore, we estimate that the total cost of reviewing this regulation is \$42,243.47 (\$221.17 × 191 commenters).

5. Impact Statement and Table

a. CY 2026 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting Medicare payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2025 to estimated payments in CY 2026. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of Medicare payments in CY 2025 and CY 2026 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD

³¹ Calculated by multiplying the mean hourly wage for medical and health service managers (SOC 11–9111) by 2 to account for overhead and fringe benefits.

facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this proposed rule, we use CY 2024 data from the Medicare Part A and Part B Common Working Files as of

February 14, 2025, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2024 claims to 2025 and 2026 using various updates. The proposed updates to the ESRD PPS base

rate are described in section II.B.4. of this proposed rule. Table 17 shows the impact of the estimated CY 2026 ESRD PPS payments compared to estimated ESRD PPS payments to ESRD facilities in CY 2025.

TABLE 17—IMPACTS OF THE PROPOSED CHANGES IN MEDICARE PAYMENTS TO ESRD FACILITIES FOR CY 2026

Facility type	Number of facilities column A	Number of treatments (in millions) column B	Routine outlier update column C (%)	Proposed budget neutral wage index update column D (%)	Proposed budget neutral non- contiguous areas payment adjustment column E (%)	Total percent change (including market basket update) column F
All Facilities	7,582	24.8	0.0	0.0	0.0	1.9
Type:						
Freestanding	7,237	23.9	0.0	0.0	0.0	1.9
Hospital-based	345	0.9	-0.4	-0.2	0.2	1.5
Ownership Type:						
Large dialysis organization	5,839	19.3	0.1	0.1	0.0	2.1
Regional chain	894	3.1	-0.4	-0.2	0.2	0.6
Independent	477	1.5	0.2	-0.3	-0.1	1.7
Hospital-based	345	0.9	-0.4	-0.2	0.2	1.5
Unknown	27	0.0	0.3	-0.6	-0.1	1.6
Geographic Location:						
Rural	1,227	3.4	0.1	-0.1	0.3	2.2
Urban	6,355	21.4	0.0	0.0	0.0	1.8
Census Region:						
East North Central	1,172	3.3	0.0	0.8	-0.1	2.6
East South Central	591	1.5	0.1	1.1	-0.1	3.1
Middle Atlantic	860	3.1	0.0	-0.9	-0.1	0.8
Mountain	429	1.4	0.0	1.0	-0.1	2.9
New England	200	0.9	0.0	-0.4	-0.1	1.4
Pacific ¹	978	4.6	-0.1	-0.7	0.5	1.4
Puerto Rico and Virgin Islands	54	0.1	0.1	0.2	-0.1	2.3
South Atlantic	1,765	5.3	0.0	0.4	-0.1	2.2
West North Central	470	1.4	0.1	0.5	-0.1	2.4
West South Central	1,063	3.2	0.0	-0.3	-0.1	1.5
Facility Size:						
Less than 3,000 treatments	714	0.8	0.0	0.3	0.0	2.2
3,000 to 3,999 treatments	476	0.8	0.0	0.2	-0.1	2.0
4,000 to 4,999 treatments	527	1.0	0.1	0.1	0.0	2.1
5,000 to 9,999 treatments	2,862	7.5	0.0	0.1	-0.1	2.0
10,000 or more treatments	3,003	14.8	0.0	-0.1	0.0	1.8
Percentage of Pediatric Patients:						
Less than 2%	7,488	24.6	0.0	0.0	0.0	1.9
Between 2% and 19%	38	0.1	0.0	0.8	0.5	3.3
Between 20% and 49%	8	0.0	-1.2	0.4	-0.1	0.3
More than 50%	48	0.0	-0.5	0.7	-0.1	2.0

¹ Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions).

Column C represents the change in payment to each ESRD facility type based on the changes to the outlier FDL and MAP amounts proposed in section II.B.3. We note that this column does not include changes associated with DefenCath® becoming outlier eligible July 1, 2026, at the end of its TDAPA period. These changes are included in column F, which shows the distributional impacts of all changes for CY 2026 ESRD PPS payments and are discussed later in this proposed rule.

Column D represents the effect of the proposed updates to the ESRD PPS wage index for CY 2026, including the continued application of the 5 percent

cap on wage index decreases and the continuation of the rural transition policy finalized in the CY 2025 ESRD PPS final rule. This update would be budget neutral, so the total impact of this proposed policy change is 0.0 percent. However, we estimate there would be distributional impacts because of this proposed update. The largest increase would be to ESRD facilities in the East South Central region, which would receive 1.1 percent higher payments because of the updated ESRD PPS wage index. The largest decrease would be for ESRD facilities in the Middle Atlantic region, which would receive 0.9 percent lower payments because of the updated ESRD PPS wage index.

Column E reflects the impact of the proposed NAPA. This proposed adjustment would be applied budget-

neutrally, so the total impact is 0.0 percent. However, we estimate there would be distributional impacts because of this proposal. Since all the non-contiguous areas which would receive this payment adjustment are located in the Pacific region, ESRD facilities in the Pacific would receive, on average, 0.5 percent higher payments, and the decrease for other regions due to budget neutrality would be 0.1 percent.

Column F reflects the overall impact of the policies discussed in this proposed rule, including the routine updates to the wage index, outlier thresholds, and post-TDAPA amounts and the newly proposed NAPA described in section II.B.8. of this proposed rule. This column also reflects the proposed ESRD PPS payment rate update for CY 2026 of 1.9 percent, which reflects the proposed ESRDB

market basket percentage increase for CY 2026 of 2.7 percent reduced by the proposed productivity adjustment of 0.8 percentage point. We expect that overall ESRD facilities would experience a 1.9 percent increase in estimated Medicare payments in CY 2026. The categories of types of ESRD facilities in the impact table show impacts ranging from a 3.3 percent increase to a 0.3 percent increase in their CY 2026 estimated Medicare payments. We note that for facility types that have a disproportionately high utilization of DefenCath®, such as regional chains, the overall spending change in column F reflects a notable decrease in CY 2026 payments. This decrease is driven by the change from DefenCath® receiving payment under the TDAPA to inclusion in the post-TDAPA calculation and becoming included in the outlier adjustment in CY 2026.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2026, we estimate that the ESRD PPS would have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2026 would be approximately \$6.9 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 0.1 percent in CY 2026.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 1.9 percent overall increase in the CY 2026 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary coinsurance payments of 1.9 percent in CY 2026, which translates to approximately \$30 million.

(5) Alternatives Considered

(a) Non-Contiguous Areas Payment Adjustment

We considered, but did not propose, implementing the NAPA without the 25 percent cap. As discussed in section II.B.8. of this proposed rule, we are proposing this new payment adjustment with a cap of 25 percent on the adjustment factor to mitigate the impact

on the ESRD PPS base rate and, therefore, mitigate the impact on payments to ESRD facilities in the contiguous U.S. and in the Caribbean territories of Puerto Rico and the U.S. Virgin Islands. We considered alternative ways to reduce the impact of this proposed payment adjustment on the ESRD PPS base rate, including the exclusion of certain areas from the scope of the adjustment. However, we believe that a cap is the most effective way to provide additional payment to ESRD facilities in these relatively higher non-labor costs, non-contiguous areas without decreasing the ESRD PPS base rate by too large a magnitude.

(b) Change to TDAPA Eligibility Timeframe

We considered alternative timelines for implementing the proposed regulatory change to the TDAPA eligibility criteria which we are proposing in a new paragraph § 413.234(c)(5). One considered alternative was to have the 3-year timeframe for eligibility apply to TDAPA applications received on or after January 1, 2026. We think this would have been a reasonable approach, as we did not identify any renal dialysis drugs or biological products that would be otherwise eligible for TDAPA but were approved by the FDA between January 1, 2020, and January 1, 2023 (3 years before the effective date of the CY 2026 ESRD PPS final rule). However, as stated in section II.B.7. of this proposed rule, we believe that by making this change effective for TDAPA applications received on or after January 1, 2028, we would allow any drug manufacturers which were operating based on the established TDAPA eligibility requirements sufficient time to prepare for their rollout. Giving manufacturers sufficient time to plan the rollout of a new renal dialysis drug or biological product would help ensure that it is made available to ESRD facilities, and therefore ESRD patients, during the TDAPA period. Since we have not at this time identified any renal dialysis drugs or biological products which were approved by the FDA prior to January 1, 2023, and have not yet applied for TDAPA, we do not believe this later implementation date would lead to any significantly-older drug or biological product applying and receiving the TDAPA.

b. Continuation of Approved Transitional Drug Add-On Payment Adjustments (TDAPA) for New Renal Dialysis Drugs or Biological Products for CY 2026

Eight renal dialysis drugs for which the TDAPA was paid in CY 2025 would continue to be eligible for the TDAPA in CY 2026: DefenCath® (taurolidine and heparin sodium), Vafseo® (vadadustat), and the oral-only phosphate binders sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate. We present our latest estimates in the following paragraphs of TDAPA spending in CY 2026, for public awareness. We are also revising our current estimates of spending for phosphate binders in CY 2025 based on preliminary data from CY 2025 ESRD PPS claims.

(1) DefenCath® (Taurolidine and Heparin Sodium)

On May 9, 2024, CMS Transmittal 12628³² implemented the 2-year TDAPA period specified in § 413.234(c)(1) for DefenCath® (taurolidine and heparin sodium). The TDAPA payment period began on July 1, 2024, and would continue through June 30, 2026. As stated previously, TDAPA payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based our impact analysis on the average monthly TDAPA payment amount for DefenCath® from the most current 72x claims data from July 2024, when utilization first appeared on the claims, through March 2025. In applying that average to each of the 6 remaining months of the TDAPA payment period in CY 2026, we estimate approximately \$40 million in spending of which, 20 percent or approximately \$10 million, would be attributed to beneficiary coinsurance amounts.

(2) Vafseo® (Vadadustat)

On November 14, 2024, CMS Transmittal 12962³³ implemented the 2-year TDAPA period specified in § 413.234(c)(1) for Vafseo® (vadadustat). On December 12, 2024, that transmittal was rescinded and replaced by

³² CMS Transmittal 12628, dated May 9, 2024, is available at <https://www.cms.gov/files/document/r12628CP.pdf>.

³³ CMS Transmittal 12962, dated November 14, 2024, was available at <https://www.cms.gov/files/document/r12962bp.pdf> <https://www.cms.gov/files/document/r12628CP.pdf>.

Transmittal 12999.³⁴ The TDAPA payment period began on January 1, 2025, and will continue through December 31, 2026. As stated previously, TDAPA payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based our impact analysis on the average monthly TDAPA payment amount for Vafseo® from the most current 72x claims data from January 2025, when utilization first appeared on the claims, through March 2025. In applying that average to each month in 2026, we estimate approximately \$30 million in spending of which, 20 percent or approximately \$10 million, would be attributed to beneficiary coinsurance amounts.

(3) Phosphate Binders

On November 14, 2024, CMS Transmittal 12962³⁵ implemented the 2-year TDAPA period specified in § 413.234(c)(1) for the following oral-only phosphate binders: sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate. On December 12, 2024, that transmittal was rescinded and replaced by Transmittal 12999.³⁶ The TDAPA payment period began on January 1, 2025, and will continue through December 31, 2026. As stated previously, TDAPA payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is

not available, the payment is based on the drug manufacturer's invoice.

In the CY 2025 ESRD PPS final rule (89 FR 89197), we estimated that total ESRD PPS spending for phosphate binders would be approximately \$870 million in CY 2025. We are revising this estimate for this CY 2026 ESRD PPS proposed rule based on our analysis of the most current 72x claims data from January 2025, when utilization first appeared on the claims, through March 2025. In January, we observed that total spending was approximately \$14 million, whereas in February and March we observed that total spending was approximately \$30 million and \$34 million, respectively. Projecting forward using the level of utilization and pricing that we observed in March 2025, we estimate approximately \$380 million in spending for phosphate binders in CY 2025, of which 20 percent, or approximately \$80 million would be attributed to beneficiary coinsurance amounts. We solicit comments on this estimate.

Similarly, using the most current 72x claims data from March 2025 we have estimated CY 2026 spending using the level of utilization and pricing that we observed in March 2025. In applying that average to each month in 2026, we estimate approximately \$410 million in spending of which 20 percent, or approximately \$80 million, would be attributed to beneficiary coinsurance amounts.

We intend to further revise the estimates for DefenCath®, Vafseo®, and the phosphate binders for the CY 2026 ESRD PPS final rule based on updated utilization and price information.

c. Payment for Renal Dialysis Services Furnished to Individuals With AKI

(1) Effects on ESRD Facilities

To understand the impact of the proposed changes affecting Medicare payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated Medicare payments in CY 2025 to estimated Medicare payments in CY 2026. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the Medicare payment estimates in CY 2025 and CY 2026 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this proposed rule, we used CY 2024 data from the Medicare Part A and Part B Common Working Files as of February 14, 2025, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2024 claims to 2025 and 2026 using various updates. The updates to the AKI dialysis payment amount are described in section III.C. of this proposed rule. Table 18 shows the impact of the estimated CY 2026 Medicare payments for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for renal dialysis services furnished to individuals with AKI in CY 2025.

TABLE 18—IMPACTS OF THE PROPOSED CHANGES IN MEDICARE PAYMENTS FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2026

Facility type	Number of facilities	Number of treatments (in millions)	Proposed ESRD PPS wage index (%)	Proposed NAPA budget neutrality factor (%)	Total impacts (including market basket update) (%)
	column A	column B	column C	column D	column F
All Facilities	5,022	277.8	0.1	−0.1	1.8
Type:					
Freestanding	4,915	273.5	0.1	−0.1	1.8
Hospital-based	107	4.4	−0.1	−0.1	1.6
Ownership Type:					
Large dialysis organization	4,154	230.0	0.1	−0.1	1.9
Regional chain	568	28.5	0.0	−0.1	1.7
Independent	185	14.7	−0.7	−0.1	1.1
Hospital-based	107	4.4	−0.1	−0.1	1.6
Unknown	8	0.3	0.1	−0.1	1.9
Geographic Location:					
Rural	823	44.6	0.0	−0.1	1.7

³⁴ CMS Transmittal 12999 dated December 12, 2024, available at <https://www.cms.gov/files/document/r12999bp.pdf>.

³⁵ CMS Transmittal 12962, dated November 14, 2024, was available at <https://www.cms.gov/files/document/r12962bp.pdf> <https://www.cms.gov/files/document/r12628CP.pdf>.

³⁶ CMS Transmittal 12999 dated December 12, 2024, available at <https://www.cms.gov/files/document/r12999bp.pdf>.

TABLE 18—IMPACTS OF THE PROPOSED CHANGES IN MEDICARE PAYMENTS FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2026—Continued

Facility type	Number of facilities	Number of treatments (in millions)	Proposed ESRD PPS wage index (%)	Proposed NAPA budget neutrality factor (%)	Total impacts (including market basket update) (%)
	column A	column B	column C	column D	column F
Urban	4,199	233.2	0.1	−0.1	1.8
Census Region:					
East North Central	824	44.7	0.7	−0.1	2.4
East South Central	374	16.7	0.9	−0.1	2.7
Middle Atlantic	544	32.3	−0.8	−0.1	0.9
Mountain	313	21.6	1.3	−0.1	3.1
New England	147	6.9	−0.4	−0.1	1.3
Pacific ¹	663	48.9	−0.7	−0.1	1.0
Puerto Rico and Virgin Islands	2	0.0	0.9	−0.1	2.6
South Atlantic	1,181	64.7	0.4	−0.1	2.2
West North Central	308	12.2	0.5	−0.1	2.2
West South Central	666	29.8	−0.3	−0.1	1.4
Facility Size:					
Less than 3,000 treatments	281	10.7	0.3	−0.1	2.1
3,000 to 3,999 treatments	267	11.2	0.2	−0.1	2.0
4,000 to 4,999 treatments	313	14.1	0.1	−0.1	1.8
5,000 to 9,999 treatments	1,960	99.2	0.1	−0.1	1.9
10,000 or more treatments	2,201	142.7	0.0	−0.1	1.8
Percentage of Pediatric Patients:					
Less than 2%	5,007	277.3	0.1	−0.1	1.8
Between 2% and 19%	14	0.5	0.3	−0.1	2.0
Between 20% and 49%	1	0.0	0.3	−0.1	2.1
More than 50%	0	0.0	0.0	0.0	0.0

¹ Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category, and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the proposed CY 2026 wage index described in section II.B.2. of this proposed rule. Column D shows the impact of the proposed NAPA budget neutrality factor, which we are applying to the proposed ESRD PPS base rate. To be clear, we are not proposing the NAPA apply to beneficiaries with AKI, so this column only reflects the impact of the budget neutrality factor associated with that policy.

Column F shows the overall impact of all policies discussed in this proposed rule, including the 1.9 percent increase to the ESRD PPS base rate, which reflects the proposed ESRDB market basket percentage increase for CY 2026 of 2.7 percent reduced by the proposed productivity adjustment of 0.8 percentage point. We expect that overall ESRD facilities will experience a 1.8 percent increase in estimated Medicare payments in CY 2026 for treatment of AKI beneficiaries. The categories of types of ESRD facilities in the impact table show impacts ranging from an increase of 0.9 percent for the Mid-Atlantic region to an increase of 3.1

percent for the Mountain region in CY 2026 estimated Medicare payments for renal dialysis services provided by ESRD facilities to individuals with AKI.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this change would have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately \$80 million would be paid to ESRD facilities in CY 2026 because of patients with AKI receiving renal dialysis services in an ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent coinsurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients will continue to be responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we expect beneficiaries to pay less coinsurance when AKI dialysis is furnished by ESRD facilities.

(5) Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI dialysis payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. Similarly, we considered proposing to apply the proposed NAPA to AKI dialysis payments. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD, and the case-mix and facility-level adjustments applied to ESRD patients may not be applicable to AKI patients, and as such, including those policies and adjustments is

inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

d. ESRD QIP

(1) Effects of the PY 2027 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to promote improvements in the quality of ESRD dialysis facility services provided to beneficiaries. The general methodology that we use to calculate a facility's TPS

is described in our regulations at § 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2027 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2027, consistent with our regulations at § 413.177.

For the PY 2027 ESRD QIP, we estimate that, of the 7,695 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 41.8 percent or 3,214 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction

for PY 2027. Among an estimated 3,214 facilities that would receive a payment reduction, approximately 60 percent or 1,926 facilities would receive the smallest payment reduction of 0.5 percent. Based on our proposals, the total estimated payment reductions for all the 3,214 facilities expected to receive a payment reduction in PY 2027 would be approximately \$22,177,163. Facilities that do not receive a TPS do not receive a payment reduction.

Table 19 shows the updated overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP.

TABLE 19—ESTIMATED DISTRIBUTION OF PY 2027 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities *
0.0%	4,248	56.9
0.5%	1,926	25.8
1.0%	897	12.0
1.5%	262	3.5
2.0%	129	1.7

* 233 facilities not scored due to insufficient data.

To estimate whether a facility would receive a payment reduction for PY 2027, we scored each facility on achievement and improvement on several clinical measures for which

there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 20) in accordance

with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 20.

TABLE 20—DATA USED TO ESTIMATE PY 2027 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
SRR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
SHR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
PPPW	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Kt/V Dialysis Adequacy Measure Topic:		
Adult HD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Pediatric HD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Adult PD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Pediatric PD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
VAT:		
% Catheter	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
STrR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
NHSN BSI	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Clinical Depression	Jan 2022–Dec 2022	Jan 2023–Dec 2023.

For all measures except the SHR clinical measure, the SRR clinical measure, the STrR measure, and the ICH CAHPS measure, measures with less than 11 eligible patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the

facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. For the ICH CAHPS measure, facilities were required to have at least 30 survey-eligible patients to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table consistent with the proposed policies

outlined in section IV.B. of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2023. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2027 for each facility resulting from this proposed rule, we multiplied the total Medicare payments

to the facility during the 1-year period between January 2023 and December 2023 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 21 shows the estimated impact of the ESRD QIP payment reductions to

all ESRD facilities for PY 2027. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding

facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2027 ESRD QIP, the actual impact of the PY 2027 ESRD QIP may vary significantly from the values provided here.

TABLE 21—ESTIMATED IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2027

	Number of facilities	Number of treatments 2023 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	7,695	27.0	7,462	3,214	−0.33
Facility Type:					
Freestanding	7,348	26.0	7,135	3,043	−0.32
Hospital-based	347	1.0	327	171	−0.50
Ownership Type:					
Large Dialysis	5,942	21.1	5,792	2,293	−0.27
Regional Chain	908	3.3	881	404	−0.38
Independent	461	1.6	444	341	−0.94
Hospital-based (non-chain)	347	1.0	327	171	−0.50
Unknown	37	0.0	18	5	−0.41
Facility Size:					
Large Entities	6,850	24.4	6,673	2,697	−0.28
Small Entities ¹	808	2.6	771	512	−0.75
Unknown	37	0.0	18	5	−0.41
Rural Status:					
(1) Yes	1,245	3.8	1,209	449	−0.28
(2) No	6,450	23.2	6,253	2,765	−0.34
Census Region:					
Northeast	1,069	4.4	1,033	450	−0.35
Midwest	1,663	5.1	1,620	703	−0.33
South	3,490	11.1	3,374	1,513	−0.35
West	1,408	6.3	1,371	501	−0.27
US Territories ²	65	0.2	64	47	−0.51
Census Division:					
Unknown	11	0.1	11	9	−0.68
East North Central	1,188	3.6	1,155	531	−0.36
East South Central	602	1.7	582	229	−0.27
Middle Atlantic	870	3.4	836	379	−0.38
Mountain	438	1.5	425	153	−0.26
New England	199	1.0	197	71	−0.26
Pacific	970	4.7	946	348	−0.27
South Atlantic	1,793	5.9	1,737	799	−0.37
West North Central	475	1.5	465	172	−0.28
West South Central	1,095	3.5	1,055	485	−0.35
US Territories ²	54	0.1	53	38	−0.48
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,207	1.5	1,071	405	−0.37
4,000–9,999 treatments	3,461	9.2	3,377	1,267	−0.28
Over 10,000 treatments	3,027	16.3	3,014	1,542	−0.38

¹ Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.

² Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

(2) Effects of the PY 2028 ESRD QIP on ESRD Facilities

For the PY 2028 ESRD QIP, we estimate that, of the 7,695 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 35.4 percent or 2,725 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2028. Among an estimated 2,725 facilities that would receive a payment reduction, approximately 62 percent or

1,694 facilities would receive the smallest payment reduction of 0.5 percent. Based on our proposals, the total estimated payment reductions for all the 2,725 facilities expected to receive a payment reduction in PY 2028 would be approximately \$18,456,799. Facilities that do not receive a TPS do not receive a payment reduction.

Table 22 shows the updated overall estimated distribution of payment

reductions resulting from the PY 2028 ESRD QIP.

TABLE 22—ESTIMATED DISTRIBUTION OF PY 2028 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities *
0.0%	4,729	63.4
0.5%	1,694	22.7
1.0%	756	10.1
1.5%	185	2.5

TABLE 22—ESTIMATED DISTRIBUTION OF PY 2028 ESRD QIP PAYMENT REDUCTIONS—Continued

Payment reduction	Number of facilities	Percent of facilities *
2.0%	90	1.2

* 241 facilities not scored due to insufficient data.

To estimate whether a facility would receive a payment reduction for PY 2028, we scored each facility on achievement and improvement on several clinical measures for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated

using the most recent data available (specified in Table 23) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 23.

TABLE 23—DATA USED TO ESTIMATE PY 2028 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Not available	Jan 2023–Dec 2023.
SRR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
SHR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
PPPW	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Kt/V Dialysis Adequacy Measure Topic:		
Adult HD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Pediatric HD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Adult PD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Pediatric PD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
VAT:		
% Catheter	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
STrR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
NHSN BSI	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Clinical Depression	Jan 2022–Dec 2022	Jan 2023–Dec 2023.

For all measures except the SHR clinical measure, the SRR clinical measure, the STrR measure, and the ICH CAHPS measure, measures with less than 11 eligible patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. For the ICH CAHPS measure, facilities were required to have at least 30 survey-eligible patients to be included in the facility's TPS. Each facility's TPS was

compared to an estimated mTPS and an estimated payment reduction table consistent with the proposed policies outlined in section IV.C. of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2023. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2028 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2023 and December 2023 by the facility's estimated payment reduction percentage expected under

the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 24 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2028. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2028 ESRD QIP, the actual impact of the PY 2028 ESRD QIP may vary significantly from the values provided here.

TABLE 24—ESTIMATED IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2028

	Number of facilities	Number of treatments 2023 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	7,695	27.0	7,454	2,725	–0.27
Facility Type:					
Freestanding	7,348	26.0	7,133	2,583	–0.27
Hospital-based	347	1.0	321	142	–0.38
Ownership Type:					
Large Dialysis	5,942	21.1	5,792	1,932	–0.22
Regional Chain	908	3.3	881	337	–0.31
Independent	461	1.6	442	309	–0.80
Hospital-based (non-chain)	347	1.0	321	142	–0.38
Unknown	37	0.0	18	5	–0.38
Facility Size:					

TABLE 24—ESTIMATED IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2028—Continued

	Number of facilities	Number of treatments 2023 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
Large Entities	6,850	24.4	6,673	2,269	−0.23
Small Entities ¹	808	2.6	763	451	−0.62
Unknown	37	0.0	18	5	−0.38
Rural Status:					
(1) Yes	1,245	3.8	1,207	362	−0.22
(2) No	6,450	23.2	6,247	2,363	−0.28
Census Region:					
Northeast	1,069	4.4	1,030	385	−0.30
Midwest	1,663	5.1	1,617	586	−0.27
South	3,490	11.1	3,373	1,309	−0.29
West	1,408	6.3	1,370	405	−0.21
U.S. Territories ²	65	0.2	64	40	−0.41
Census Division:					
Unknown	11	0.1	11	7	−0.54
East North Central	1,188	3.6	1,155	446	−0.29
East South Central	602	1.7	582	177	−0.21
Middle Atlantic	870	3.4	834	327	−0.32
Mountain	438	1.5	425	126	−0.21
New England	199	1.0	196	58	−0.20
Pacific	970	4.7	945	279	−0.21
South Atlantic	1,793	5.9	1,736	706	−0.31
West North Central	475	1.5	462	140	−0.20
West South Central	1,095	3.5	1,055	426	−0.29
US Territories ²	54	0.1	53	33	−0.38
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,207	1.5	1,063	327	−0.28
4,000–9,999 treatments	3,461	9.2	3,377	1,055	−0.22
Over 10,000 treatments	3,027	16.3	3,014	1,343	−0.32

¹ Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.

² Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

(3) Effects on the Medicare Program

For PY 2027, we estimate that the ESRD QIP would contribute approximately \$22,177,163 in Medicare savings. For PY 2028, we estimate that the ESRD QIP would contribute approximately \$18,456,799 in Medicare savings. For comparison, Table 25 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2028.

TABLE 25—ESTIMATED ESRD QIP AGGREGATE PAYMENT REDUCTIONS FOR PAYMENT YEARS 2018 THROUGH 2028

Payment year	Estimated payment reductions
PY 2028	\$18,456,799.
PY 2027	\$22,177,163.
PY 2026	\$15,990,524 (88 FR 76500).
PY 2025	\$32,457,693 (87 FR 67297).
PY 2024	\$17,104,031 (86 FR 62011).
PY 2023	\$5,548,653 (87 FR 67297).
PY 2022	\$0 ³⁷ (86 FR 62011).
PY 2021	\$32,196,724 (83 FR 57062).
PY 2020	\$31,581,441 (81 FR 77960).
PY 2019	\$15,470,309 (80 FR 69074).
PY 2018	\$11,576,214 (79 FR 66257).

(4) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program's inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We continue to monitor and evaluate trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more by examining these impacts through the analysis of available data from our existing measures.

(5) Alternatives Considered

In section IV.C.2. of this proposed rule, we are proposing to update the ICH CAHPS clinical measure by removing questions from the ICH CAHPS Survey beginning with PY 2028. We considered not proposing this change. However, we concluded that reducing the length of the ICH CAHPS Survey would help to mitigate ongoing concerns regarding patient burden due to survey fatigue and lead to increased survey response rates, thereby more comprehensively capturing the experience of in-center hemodialysis patients through the ICH CAHPS clinical measure.

e. ETC Model

(1) Overview

The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), the CY 2023 ESRD PPS final rule (87 FR 67136), and the CY 2024 ESRD PPS final rule (88 FR 76344) for ESRD facilities and for Managing Clinicians for claims

with dates of service from January 1, 2021 to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C. For the results of the detailed economic analysis of the ETC Model and a description of the methodology used to perform the analysis, see the Specialty Care Models final rule (85 FR 61114).

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the ETC Model relative to baseline expenditures that use actual data for MYs 1–3 and updated methodology.

Results were generated from an average of 400 simulations. The datasets and risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

Table 26 is provided to isolate the total impact of terminating the ETC Model on December 31, 2025 by displaying the projected impact to Medicare for the PYs that will no longer be included in the ETC Model. Negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase in Medicare spending. We estimate that

the Medicare program would increase program spending by a net total of \$5 million from the PPA between January 1, 2026, and June 30, 2027, less \$6 million from training and education expenditures that will not occur due to the model ending. Therefore, the net impact to Medicare spending from terminating the model early is estimated to be \$1 million in savings during the final 18 months of the performance period (January 1, 2026–June 30, 2027).

(3) Medicare Estimate—Impact of Model Termination Effective December 31, 2025

TABLE 26—ESTIMATES OF IMPACT ON MEDICARE PROGRAM SPENDING (ROUNDED \$M) FOR ENDING THE ESRD TREATMENT CHOICES (ETC) MODEL ON DECEMBER 31, 2025

[Estimates represent the reversal of impacts otherwise projected if the model were to finish originally-specified testing period]

	2026	2027	1.5 Year total *
Net Impact to Medicare Spending	–2	1	–1
Overall PPA Net & HDPa	1	4	5
Clinician PPA Downward Adjustment	4	3	7
Clinician PPA Upward Adjustment	–5	–2	–7
Clinician PPA Net	0	0	0
Clinician HDPa			
Facility Downward Adjustment	46	27	73
Facility Upward Adjustment	–45	–23	–68
Facility PPA Net	1	4	5
Facility HDPa			
Total PPA Downward Adjustment	50	30	80
Total PPA Upward Adjustment	–50	–25	–75
Total PPA Net	1	4	5
Total HDPa			
KDE Benefit Costs	–1	–1	–2
HD Training Costs	–2	–2	–4

* Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The kidney disease patient education services benefit costs are less than \$1M each year but are rounded up to \$1M to show what years they apply to.

The ETC Model Second Annual Evaluation Report (2024)³⁸ examined the impact of the ETC Model through 2022 and found that during the first 2 calendar years of the model, there was no evidence of an impact of the ETC Model on the use of home dialysis modalities, transplant waitlisting, and living donor transplantation, which are the direct targets of the model's payment adjustments. Therefore, the impact of terminating the ETC Model early is simply the negation of the projected performance and other payments for PYs 2026 and 2027 of the model, which are very small on net for that period.

Table 26 uses the assumptions for the performance payment adjustments, kidney disease patient education (KDE) services, and HD training add-ons that were used in the CY 2025 ESRD PPS final rule (89 FR 89209). There is no impact reported for the Home Dialysis Payment Adjustment (HDPa) because

the HDPa applied only to claims with claim service dates beginning January 1, 2021 and ending December 31, 2023. In contrast to what was reported in CY 2025 ESRD PPS final rule (89 FR 89209), Table 26 uses actual HDPa counts and actual PPAs for MYs 1–3 (which align with PYs 2022 and 2023). Partial estimates based on actual data were available for PY 2024 and were incorporated into the model for that year. The ETC model's projections were used for PYs 2025–2027. If we had not updated our baseline model projection for actual experience, then the net impact to Medicare spending would not have resulted in savings to Medicare.

Table 26 also includes two updates to the methodology used to generate the estimate. In the CY 2025 ESRD PPS final rule (89 FR 89209) estimates, we interpreted the *percentage* improvement in the ETC participant's MY performance on the home dialysis rate and transplant rate relative to the

Benchmark Year rate to be a “percentage point improvement” rather than a relative percentage increase. In Table 26, we revised the baseline model's improvement scoring methodology to award improvement points based on relative improvement (this was the original intent of the ETC Model's design). For example, a facility with benchmark home dialysis rate of 5 percent and MY home dialysis rate of 6 percent is now measured to have 20 percent improvement in the home dialysis rate (relative improvement) instead of only 1 percentage point of improvement. No additional changes were made to the improvement thresholds or points awarded used in the improvement scoring methodology. A minor update was also made to the rolling benchmark used in the home dialysis rate calculation to reflect the fact that hospital referral regions not randomized to participate in the ETC

model saw increases in their home dialysis rate during the initial MYs of the model. We modified the rolling benchmark from assuming that hospital referral regions not randomized to participate in the ETC model would have a static home dialysis rate to restricting the geographies included in the model to only be those hospital referral regions that were actually randomized into the model. The values estimated by the model for PYs 2021–2024 were validated against actual reported spending in the HDPa and PPA categories.

(4) Effects on the Home Dialysis Rate, the Transplant Rate, and Kidney Transplantation

The change proposed in this rule is not expected to impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017). The ETC Model Second Annual Evaluation Report examined the impact of the model through 2022 and found that during the first 2 calendar years of the model, there

was no evidence of an impact of the ETC Model on the use of home dialysis modalities, transplant waitlisting, and living donor transplantation. Therefore, terminating the model early is not expected to have an impact on these trends.

(5) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The change in this proposed rule will end the kidney disease patient education services and HD training add-ons described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017) for the final two PYs of the model.

(6) Effects on Medicare Beneficiaries

The proposal to terminate the model early is not expected to impact the findings reported for the effects of ETC Model on Medicare beneficiaries. Further details on the impact of the ETC Model on ESRD Beneficiaries may be found in the Specialty Care Models final rule (85 FR 61357) and the CY 2022 ESRD PPS final rule (86 FR 61874).

(7) Alternatives Considered

The Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), the CY 2023 ESRD PPS final rule (87 FR 67136), the CY 2024 ESRD PPS final rule (88 FR 76344), CY 2025 ESRD PPS final rule (89 FR 89084), and the proposed policy herein address a model specific to ESRD. These rules provide descriptions of the requirements that we waive, identify the performance metrics and payment adjustments to be tested, and presents rationales for our changes, and where relevant, alternatives considered. For context related to alternatives previously considered when establishing and modifying the ETC Model we refer readers to section V.B. of this proposed rule and to the previous citations.

D. Accounting Statement

Consistent with OMB Circular A–4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), we have prepared an accounting statement in Table 27 showing the classification of the impact associated with the provisions of this proposed rule.

TABLE 27—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

Category	Transfers
ESRD PPS and AKI (CY 2026)	
Annualized Monetized Transfers	\$130 million.
Bearers of Transfer Gain	Medicare ESRD Facilities.
Increased Beneficiary Co-insurance Payments	\$30 million.
Bearers of Transfer Gain	Medicare ESRD Facilities.
ESRD QIP for PY 2027	
Annualized Monetized Transfers	\$22.1 million.
Bearers of Transfer Gain	Federal Government.
ESRD QIP for PY 2028	
Annualized Monetized Transfers	\$18.4 million.
Bearers of Transfer Gain	Federal Government.
ETC Model for PYs 2026–2027	
Annual Monetized Transfers	\$1 million.
Bearers of Transfer Gain	Federal Government.

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, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We do not believe ESRD facilities are operated by small government entities such as

counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity. Therefore, the number of small entities estimated in this RFA analysis includes the number of ESRD facilities that are either considered small businesses or nonprofit organizations.

According to the Small Business Administration’s (SBA) size standards, an ESRD facility is classified as a small business if it has average revenues of less than \$47 million across the past 5 years.³⁹ For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by large dialysis organizations (LDOs) and

³⁹ <http://www.sba.gov/content/small-business-size-standards>.

regional chains, which would have total revenues of more than \$6.5 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because we lack data on individual ESRD facilities' receipts, we cannot determine the number of small proprietary ESRD facilities or the proportion of ESRD facilities' revenue derived from Medicare FFS payments. Therefore, we assume that all ESRD facilities that are not owned by LDOs or regional chains are considered small businesses. Accordingly, we consider the 477 ESRD facilities that are independent and 345 ESRD facilities that are hospital-based, as shown in the ownership category in Table 17, to be small businesses. These ESRD facilities represent approximately 11 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 775 ESRD facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 362 nonprofit ESRD facilities that are also considered small businesses, there are 1,235 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

As its measure of significant economic impact on a substantial number of small entities, HHS's practice in interpreting the RFA is to consider effects economically "significant" on a "substantial" number of small entities only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. As shown in Table 17, we estimate that the overall revenue impact of this proposed rule on all ESRD facilities is a positive increase to Medicare FFS payments by approximately 1.9 percent. For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 1.5 percent increase in Medicare FFS payments for CY 2026. An independent facility (as defined by ownership type) is likewise estimated to receive a 1.7 percent increase in Medicare FFS payments for CY 2026. Although not displayed in Table 17, we have found that among the 822 ESRD facilities that are small businesses, those furnishing fewer than 3,000 treatments per year are estimated to receive a 2.0 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated

to receive a 1.6 percent increase in Medicare FFS payments. Additionally, among the 775 nonprofit ESRD facilities, those furnishing fewer than 3,000 treatments per year are estimated to receive a 1.6 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated to receive a 1.1 percent increase in Medicare FFS payments.

For AKI dialysis, we are unable to estimate whether patients would go to certain types of ESRD facilities, however, we have estimated there is a potential for \$80 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities that are small businesses or nonprofits.

Based on the estimated Medicare payment impacts described previously, we believe that the change in revenue threshold will be reached by some categories of small entities as a result of the policies in this proposed rule. This analysis is based on the assumptions described earlier in this section of this proposed rule as well as the detailed impact analysis discussed in section VIII.C. of this proposed rule, which includes a discussion of data sources, general assumptions, and alternatives considered.

For the ESRD QIP, we estimate that of the 3,214 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2027 ESRD QIP, 512 are ESRD small entity facilities. We present these findings in Table 19 ("Estimated Distribution of PY 2027 ESRD QIP Payment Reductions") and Table 21 ("Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027"). Table 19 shows the overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP. Table 21 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2027, and also details the distribution of ESRD facilities by size, geography, and facility type. We also estimate that of the 2,725 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2028 ESRD QIP, 451 are ESRD small entity facilities. We present these findings in Table 22 ("Estimated Distribution of PY 2028 ESRD QIP Payment Reductions") and Table 24 ("Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2028"). Table 22 shows the overall estimated distribution of payment reductions resulting from the PY 2028 ESRD QIP. Table 24 shows the estimated impact of the ESRD QIP payment reductions to all ESRD

facilities for PY 2028, and also details the distribution of ESRD facilities by size, geography, and facility type.

Regarding the ETC Model, we estimate \$1 million in savings to Medicare from proposing to terminate the Model effective December 31, 2025.

Therefore, the Secretary has determined that this proposed rule will have a significant economic impact, reflecting a positive revenue increase, on a substantial number of small entities. This RFA section along with the RIA constitutes our proposed regulatory flexibility analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 111 rural hospital-based ESRD facilities, we do not know how many of them are hospital-based with fewer than 100 beds. However, overall, the 111 rural hospital-based ESRD facilities would experience an estimated 2.2 percent increase in payments. 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 2025, that threshold is approximately \$187 million. We do not interpret Medicare payment rules as being unfunded mandates but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, State, local, or Tribal. Therefore, this proposed rule does not mandate any requirements for State, local, or Tribal governments, or for the private sector.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of State, local, or Tribal government.

H. Executive Order 14192, “Unleashing Prosperity Through Deregulation”

Executive Order 14192, entitled “Unleashing Prosperity Through Deregulation” was issued on January 31, 2025, and requires that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.” The updates proposed for the ESRD QIP do not create new regulations, nor do the proposals create new incremental costs. We estimate that these proposals, if finalized, would generate approximately \$15.4 million in annualized cost savings relative to PY 2027 based on currently available facility and patient data. Therefore, the updates proposed for the ESRD QIP would be considered an Executive Order 14192 deregulatory action if finalized as proposed.

IX. Files Available to the Public

The Addenda for the annual ESRD PPS proposed and final rule will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and will be posted on CMS’s website under the regulation number, CMS–1830–P, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDPayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>. In addition to the Addenda, limited data set files (LDS) are available for purchase at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile>. Readers who experience any problems accessing the Addenda or LDS files, should contact CMS by sending an email to CMS at the following mailbox: ESRDPayment@cms.hhs.gov.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid

Services, approved this document on June 27, 2025.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.230 is amended by revising paragraph (a) to read as follows:

§ 413.230 Determining the per treatment payment amount.

* * * * *

(a) The per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in §§ 413.232, 413.233, and 413.235 of this part;

* * * * *

■ 3. Section 413.233 is revised to read as follows:

§ 413.233 Additional facility-level adjustments.

(a) CMS adjusts the base rate for facilities in rural areas, as defined in § 413.231(b)(2).

(b) CMS adjusts the non-labor-related portion of the base rate for facilities in Alaska, Hawaii, Guam, American Samoa, and the Northern Mariana Islands.

■ 4. Section 413.234 is amended—

■ a. In paragraph (a), by revising the definition of “New renal dialysis drug or biological product”;

■ b. By revising paragraphs (b)(1)(ii) and (b)(2)(ii);

■ c. By adding paragraph (c)(5); and

■ d. By revising paragraph (g)(5).

The revisions and additions read as follows:

§ 413.234 Drug designation process.

(a) * * *

New renal dialysis drug or biological product. An injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the Food and Drug Administration (FDA) on or after January 1, 2020, under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, be commercially available, and be designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.

* * * * *

(b) * * *

(1) * * *

(ii) If the new renal dialysis drug or biological product meets the requirements in paragraph (c)(5) of this section and is not excluded under paragraph (e) of this section, the new drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section.

* * * * *

(2) * * *

(ii) If the new renal dialysis drug or biological product meets the requirements in paragraph (c)(5) of this section, the new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(2) of this section; and

* * * * *

(c) * * *

(5) CMS provides for a transitional drug add-on payment adjustment (as specified in paragraphs (c)(1) and (2) of this section) to an ESRD facility for furnishing a new renal dialysis drug or biological product if the new drug or biological product meets the following requirements:

(i) Has a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures; and

(ii) Has submitted a complete application for the transitional drug add-on payment adjustment to CMS prior to January 1, 2028, or within three years of FDA approval under section 505 of the Federal Food, Drug, and

Cosmetic Act or section 351 of the Public Health Service Act.

* * * * *

(g) * * *

(5) The post-TDAPA add-on payment adjustment that is applied to an ESRD PPS claim is adjusted by any applicable patient-level case-mix adjustments under § 413.235.

* * * * *

PART 512—STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR THE RADIATION ONCOLOGY MODEL AND THE END-STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 5. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315(a), and 1395hh.

■ 6. Section 512.320 is amended by revising to read as follows:

§ 512.320 Duration.

CMS will apply the payment adjustments described in this subpart under the ETC Model to claims with claim service dates beginning on or after January 1, 2021, and ending on or before December 31, 2025.

■ 7. Section 512.355 is amended by revising paragraphs (a) and (b); and table 1 to paragraph (c) to read as follows:

§ 512.355 Schedule of performance assessment and performance payment adjustment.

(a) *Measurement Years.* CMS assesses ETC Participant performance on the home dialysis rate and the transplant rate during each of the MYs. The first MY begins on January 1, 2021, and the final MY ends on December 31, 2024.

(b) *Performance Payment Adjustment Period.* CMS adjusts payments for ETC Participants by the PPA during each of the PPA Periods, each of which corresponds to a MY. The first PPA Period begins on July 1, 2022, and the final PPA Period ends on December 31, 2025.

(c) * * *

TABLE 1 TO PARAGRAPH (c)—ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS

Measurement year (MY)	Performance payment adjustment (PPA) period
MY 1—1/1/2021 through 12/31/2021	PPA Period 1—7/1/2022 through 12/31/2022.
MY 2—7/1/2021 through 6/30/2022	PPA Period 2—1/1/2023 through 6/30/2023.
MY 3—1/1/2022 through 12/31/2022	PPA Period 3—7/1/2023 through 12/31/2023.
MY 4—7/1/2022 through 6/30/2023	PPA Period 4—1/1/2024 through 6/30/2024.
MY 5—1/1/2023 through 12/31/2023	PPA Period 5—7/1/2024 through 12/31/2024.
MY 6—7/1/2023 through 6/30/2024	PPA Period 6—1/1/2025 through 6/30/2025.
MY 7—1/1/2024 through 12/31/2024	PPA Period 7—7/1/2025 through 12/31/2025.

■ 8. Section 512.360 is amended by revising paragraph (c)(2)(iii) introductory text to read as follows:

§ 512.360 Beneficiary population and attribution.

* * * * *

(c) * * *

(2) * * *

(iii) For MY3 through MY7, a Pre-emptive LDT Beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to the Managing Clinician who submitted the most claims for services furnished to the beneficiary in the 365 days preceding the date in which the beneficiary received the transplant.

* * * * *

■ 9. Section 512.365 is amended by revising paragraphs (b)(1)(ii) introductory text, (b)(2)(ii) introductory text, (c)(1)(i)(A) introductory text, (c)(1)(ii)(A), (c)(2)(i)(A), (c)(2)(ii)(A)(1) and (2) to read as follows:

§ 512.365 Performance assessment.

* * * * *

(b) * * *

(1) * * *

(ii) For MY3 through MY7, the numerator is the total number of home dialysis treatment beneficiary years, plus one half the total number of self dialysis treatment beneficiary years,

plus one half the total number of nocturnal in center dialysis beneficiary years for attributed ESRD Beneficiaries during the MY.

* * * * *

(2) * * *

(ii) For MY3 through MY7, the numerator is the total number of home dialysis treatment beneficiary years, plus one half the total number of self dialysis treatment beneficiary years, plus one half the total number of nocturnal in center dialysis beneficiary years for attributed ESRD Beneficiaries during the MY.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who

were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY.

* * * * *

(ii) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a diagnosis of vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(1) of this section. Months in

which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(2) of this section.

* * * * *

(2) * * *

(i) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a diagnosis of vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(1) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(2) of this section.

* * * * *

(ii) * * *

(A) * * *

(1) Dialysis treatment beneficiary years included in the denominator are

composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a vital solid organ cancer diagnosis are identified as described in paragraph (c)(1)(i)(A)(1) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(2) of this section.

(2) MY1 and MY2, Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant. For MY3 through MY7, Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant, excluding beneficiaries who had a vital solid organ cancer diagnosis and were

receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a vital solid organ cancer diagnosis are identified as described in paragraph (c)(1)(i)(A)(1) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(2) of this section. Pre-emptive LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

* * * * *

■ 10. Section 512.370 is amended by revising paragraph (b) introductory text, table 1 to paragraph (b)(1), and paragraphs (b)(2) introductory text, (b)(3), (c) introductory text, (c)(1)(v), and (d)(2) to read as follows:

§ 512.370 Benchmarking and scoring.

* * * * *

(b) *Achievement Scoring.* CMS assesses ETC Participant performance at the aggregation group level on the home dialysis rate and transplant rate against achievement benchmarks constructed based on the home dialysis rate and transplant rate among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. Achievement benchmarks are calculated as described in paragraph (b)(1) of this section and, for MY3 through MY7, are stratified as described in paragraph (b)(2) of this section. For MY5 through MY7, the ETC Participant's achievement score is subject to the restriction described in paragraph (b)(3) of this section.

(1) * * *

TABLE 1 TO § 512.370(b)(1)—ETC MODEL SCHEDULE OF PPA ACHIEVEMENT BENCHMARKS BY MEASUREMENT YEAR

MY1 and MY2	MY3 and MY4	MY5 and MY6	MY7	Points
90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	2
75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.5
50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1
30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	0.5
<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	0

(2) *Stratifying achievement benchmarks.* For MY3 through MY7, CMS stratifies achievement benchmarks

based on the proportion of beneficiary years attributed to the aggregation group for which attributed beneficiaries are

dual eligible or LIS recipients during the MY. An ESRD Beneficiary or Pre-emptive LDT Beneficiary is considered

to be dual eligible or a LIS recipient for a given month if at any point during the month the beneficiary was dual eligible or an LIS recipient based on Medicare administrative data. CMS stratifies the achievement benchmarks into the following two strata:

* * * * *

(3) For MY5 through MY7, CMS will assign an achievement score to an ETC Participant for the home dialysis rate or the transplant rate only if the ETC Participant's aggregation group has a home dialysis rate or a transplant rate greater than zero for the MY.

(c) *Improvement scoring.* CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate against benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year to calculate the ETC Participant's improvement score, as specified in paragraph (c)(1) of this section. For MY3 through MY7, CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate for ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, who are dual eligible or LIS recipients to determine whether to

add the Health Equity Incentive to the ETC Participant's improvement score, as specified in paragraph (c)(2) of this section.

(1) * * *

(v) For MY3 through MY7, when calculating improvement benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year, CMS adds one beneficiary month to the numerator of the home dialysis rate and adds one beneficiary month to the numerator of the transplant rate, such that the Benchmark Year rates cannot be equal to zero.

* * * * *

(d) * * *

(2) For MY3 through MY7, CMS calculates the ETC Participant's MPS as the higher of the ETC Participant's achievement score for the home dialysis rate or the sum of the ETC Participant's improvement score for the home dialysis rate calculated as specified in paragraph (c)(1) of this section and, if applicable, the Health Equity Incentive, calculated as described in paragraph (c)(2)(i) of this section, together with the higher of the ETC Participant's achievement score for the transplant

rate or the sum of the ETC Participant's improvement score for the transplant rate calculated as specified in paragraph (c)(1) of this section and, if applicable, the Health Equity Incentive, calculated as described in paragraph (c)(2)(ii) of this section, weighted such that the ETC Participant's score for the home dialysis rate constitutes $\frac{2}{3}$ of the MPS and the ETC Participant's score for the transplant rate constitutes $\frac{1}{3}$ of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS for MY3 through MY7:

Modality Performance Score = $2 \times$
(Higher of the home dialysis achievement or (home dialysis improvement score + Health Equity Bonus $\dagger$)) + (Higher of the transplant achievement or (transplant improvement score + Health Equity Bonus $\dagger$))

$\dagger$ The Health Equity Incentive is applied to the home dialysis improvement score or transplant improvement score only if earned by the ETC Participant.

■ 11. Section 512.380 is amended by revising tables 1 and 2 to § 512.380 to read as follows:

§ 512.380 PPA Amounts and schedules.

* * * * *

TABLE 1 TO § 512.380—FACILITY PPA AMOUNTS AND SCHEDULE

	MPS	Performance payment adjustment period			
		1 and 2 (%)	3 and 4 (%)	5 and 6 (%)	7 (%)
Facility Performance Payment Adjustment	≤6	+4.0	+5.0	+6.0	+7.0
	≤5	+2.0	+2.5	+3.0	+3.5
	≤3.5	0	0	0	0
	≤2	−2.5	−3.0	−3.5	−4.5
	≤5	−5.0	−6.0	−7.0	−9.0

TABLE 2 TO § 512.380—CLINICIAN PPA AMOUNTS AND SCHEDULE

	MPS	Performance payment adjustment period			
		1 and 2 (%)	3 and 4 (%)	5 and 6 (%)	7 (%)
Clinician Performance Payment Adjustment	≤6	+4.0	+5.0	+6.0	+7.0
	≤5	+2.0	+2.5	+3.0	+3.5
	≤3.5	0	0	0	0
	≤2	−2.5	−3.0	−3.5	−4.0
	≤5	−5.0	−6.0	−7.0	−8.0

■ 12. Section 512.390 is amended by revising paragraph (b) introductory text to read as follows:

§ 512.390 Notification, data sharing, and targeted review.

* * * * *

(b) Data sharing with ETC Participants. CMS shares certain

beneficiary-identifiable data as described in paragraph (b)(1) of this section and certain aggregate data as described in paragraph (b)(2) of this section with ETC Participants regarding their attributed beneficiaries and performance under the ETC Model. Data

will not be shared after November 30, 2025.

Robert F. Kennedy, Jr.,
Secretary, Department of Health and Human Services.

[FR Doc. 2025–12368 Filed 6–30–25; 4:15 pm]

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